

SUBJECT NARRATIVES

Primary Reason for Narrative

Subject Number

Death

Subject C4591001 1152 11521085 (also
Life-Threatening Serious Adverse Event)
Subject C4591001 1156 11561124 (also
Life-Threatening Serious Adverse Event)

Life-Threatening Serious Adverse Event

Subject C4591001 1007 10071276
Subject C4591001 1081 10811135
Subject C4591001 1083 10831060
Subject C4591001 1091 10911197
Subject C4591001 1091 10911300
Subject C4591001 1095 10951173
Subject C4591001 1109 11091204
Subject C4591001 1109 11091448
Subject C4591001 1117 11171036
Subject C4591001 1124 11241106
Subject C4591001 1140 11401009
Subject C4591001 1141 11411153
Subject C4591001 1142 11421084
Subject C4591001 1218 12181057
Subject C4591001 1226 12261300
Subject C4591001 1231 12312854
Subject C4591001 1251 12511239

Safety-Related Subject Withdrawal

Subject C4591001 1012 10121163
Subject C4591001 1015 10151134
Subject C4591001 1016 10161087
Subject C4591001 1027 10271105
Subject C4591001 1087 10871354
Subject C4591001 1090 10901507
Subject C4591001 1125 11251243
Subject C4591001 1134 11341153
Subject C4591001 1134 11341174
Subject C4591001 1163 11631059
Subject C4591001 1166 11661047
Subject C4591001 1178 11781107

Subject C4591001 1224 12241065
Subject C4591001 1226 12261072
Subject C4591001 1231 12315429
Subject C4591001 1246 12461025

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1152 11521085; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 19AUG2020; Date of Last Dose: 19AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1978	42	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
172.72 cm	84.09 kg	28.1 kg/m2	19AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
chronic sinusitis	Chronic sinusitis	2000	Present
seasonal allergies	Seasonal allergy	2000	Present
breast cancer	Breast cancer	2001	Past
lumpectomy left breast	Breast conserving surgery	2001	Past
breast cancer	Breast cancer	2017	Past
lumpectomy left breast	Breast conserving surgery	2017	Past

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1152 11521085; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 19AUG2020; Date of Last Dose: 19AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	19AUG2020 (1)	10:38

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Death	UNDETERMINED CAUSE OF DEATH	26AUG2020 (8)		26AUG2020 (8)		1	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	P/W	Y	Fatal (26AUG2020)	NOT RELATED/OTHER: UNDETERMINED CAUSE OF DEATH	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1152 11521085; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 19AUG2020; Date of Last Dose: 19AUG2020

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	19AUG2020	
Withdrawn	VACCINATION	26AUG2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	26AUG2020	DEATH

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1152 11521085; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 19AUG2020; Date of Last Dose: 19AUG2020

Narrative Comment

Subject C4591001 1152 11521085, a 42-year-old white female with a pertinent medical history of recurrent breast cancer (in 2001 and 2017), treated with lumpectomy and radiation on unknown dates, and implantation of an Essure permanent birth control device (implanted in 2017), received Dose 1 on 19 Aug 2020. The subject was not taking any concomitant medications. The subject died (cause of death was undetermined) on 26 Aug 2020, 7 days after receiving Dose 1.

The subject's husband stated that the subject had no adverse events after receiving Dose 1. On 25 Aug 2020 (Day 7), she had a normal evening and went to bed. On 26 Aug 2020 (Day 8), the husband found that the subject had died and the cause of death was undetermined. On 02 Jan 2021, the subject's husband reported that the medical examiner stated that the subject died from sudden cardiac failure brought on by 2 rounds of radiation for recurring breast cancer, which weakened her heart. The subject had no changes in her health and medications. Essure was still in place at the time of death. The investigator felt that the cause of death was sudden cardiac failure from radiation therapy on 2 separate occasions for breast cancer. However, this could not be confirmed. During the follow-up report, it was reported that the medical examiner's office determined the cause of death as "undetermined." An autopsy was performed and the results were still pending at the time of this report.

In the opinion of the investigator, there was no reasonable possibility that the death was related to the study intervention. The investigator further stated that although the full autopsy report was pending and determining cause of death at this time was essentially an educated guess, the subject had possible risk factors. She possibly had a thromboembolic event related to a history of breast cancer, or there was a potential toxicity related to the Essure permanent birth control device. The subject had an Essure implant since 2017 for permanent birth control that was taken off the market in the United States by the Food and Drug Administration (FDA) in 2018. A brief review revealed almost 50,000 reports to the FDA regarding the device and approximately 50 deaths. The investigator stated that Essure was a concomitant device that was a cosuspect in the subject's death. Pfizer concurred with the investigator's causality assessment.

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1156 11561124; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 10SEP2020; Date of Last Dose: 02OCT2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1967	53	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
181.2 cm	98.1 kg	29.9 kg/m2	10SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
anxiety	Anxiety	NOV2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	10SEP2020 (1)	12:16
2	Placebo	02OCT2020 (23)	10:39

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1156 11561124; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 10SEP2020; Date of Last Dose: 02OCT2020

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Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	INJ&P	Overdose	MULTIPLE DRUG OVERDOSE	02NOV2020 (54)		02NOV2020 (54)		1
2	RESP	Respiratory arrest	RESPIRATORY ARREST	02NOV2020 (54)		02NOV2020 (54)		1

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	W	Y	Fatal (02NOV2020)	NOT RELATED/OTHER: DRUG OVERDOSE	2	32	Y
2	4	W	Y	Fatal (02NOV2020)	NOT RELATED/OTHER: DRUG OVERDOSE	2	32	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Death

Unique Subject ID: C4591001 1156 11561124; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 10SEP2020; Date of Last Dose: 02OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10SEP2020	
Withdrawn	VACCINATION	02NOV2020	DEATH
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	02NOV2020	DEATH

Narrative Comment
<p>Subject C4591001 1156 11561124, a 53-year-old white male with a pertinent medical history of former tobacco use (from an unknown date to 2019), anxiety (since Nov 2018), overweight (since an unknown date), and family history of myocardial infarction, received Dose 1 on 10 Sep 2020 and Dose 2 on 02 Oct 2020 (Day 23). On 02 Nov 2020, the subject died of respiratory arrest following a multiple drug overdose, 31 days after receiving Dose 2.</p> <p>Concomitant medication included alprazolam (since 15 Oct 2018) for anxiety.</p> <p>On 02 Nov 2020 (Day 54), the subject had a multiple drug overdose that resulted in respiratory arrest, and was found deceased at his residence.</p> <p>An autopsy report revealed accidental death due to intoxication with fentanyl, despropionyl fentanyl (4-ANPP), ethanol (all since unknown dates), and alprazolam, which were used as recreational drugs at unknown doses.</p> <p>In the opinion of the investigator, there was no reasonable possibility that the multiple drug overdose and respiratory arrest were related to the study intervention or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.</p>

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1007 10071276; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 26AUG2020; Date of Last Dose: 17SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1977	43	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
187 cm	91.4 kg	26.1 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Seasonal allergy	Seasonal allergy	1987	Present
Asthma	Asthma	1990	Present
Vasectomy	Vasectomy	2016	Past

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1007 10071276; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 26AUG2020; Date of Last Dose: 17SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	26AUG2020 (1)	15:11
2	Placebo	17SEP2020 (23)	14:33

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NEOPL	Chronic myeloid leukaemia	chronic myelogenous leukemia	24SEP2020 (30)		ONGOING			4
2	BLOOD	Leukocytosis	leukocytosis	24SEP2020 (30)		19OCT2020 (55)		26	3
3	BLOOD	Thrombocytosis	thrombocytosis	24SEP2020 (30)		26OCT2020 (62)		33	3

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: Genetic change in stem cells	2	8	Y
2	N	N	Resolved (19OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N
3	N	N	Resolved (26OCT2020)	NOT RELATED/OTHER: Chronic myelogenous leukemia	2	8	N

Prohibited Concomitant Medications				
Investigator Text	WHO Drug Preferred Term	Start Date	End Date	Route
Dasatinib	DASATINIB	06OCT2020	ONGOING	ORAL

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1007 10071276; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 26AUG2020; Date of Last Dose: 17SEP2020

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Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
SARS-CoV-2 vaccination Pfizer	TOZINAMERAN	30DEC2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	30DEC2020	PROTOCOL DEVIATION

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1081 10811135; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 31AUG2020; Date of Last Dose: 22SEP2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1971	48	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
177.8 cm	110.82 kg	35 kg/m2	31AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	31AUG2020 (1)	12:15
2	Placebo	22SEP2020 (23)	12:18

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1081 10811135; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 31AUG2020; Date of Last Dose: 22SEP2020

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	CARD	Coronary artery disease	Coronary Artery disease	04NOV2020 (66)		ONGOING		
2	VASC	Essential hypertension	New onset Essential Hypertension	31AUG2020 (1)	12:11	ONGOING		
3	METAB	Hyperlipidaemia	New onset Unspecified Hyperlipidemia	29OCT2020 (60)		ONGOING		
4	CARD	Myocardial infarction	Myocardial Infarction	21OCT2020 (52)		28OCT2020 (59)		8
5	METAB	Type 2 diabetes mellitus	Type II Diabetes Mellitus	27OCT2020 (58)		ONGOING		

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC/TCN	N	Yes	NOT RELATED/OTHER: Idiopathic	2	44	N
2	2	TC	N	Yes	NOT RELATED/OTHER: Idiopathic	1	1	N
3	2	TC	N	Yes	NOT RELATED/OTHER: Idiopathic	2	38	N
4	4	TC/TCN	Y	Resolved (28OCT2020)	NOT RELATED/OTHER: Cardiac Event	2	30	Y
5	3	TC	Y	Yes	NOT RELATED/OTHER: Insulin Resistance	2	36	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Other SAE
Unique Subject ID: C4591001 1081 10811135; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 31AUG2020; Date of Last Dose: 22SEP2020

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Flu Vaccination	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	21OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1083 10831060; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 06AUG2020; Date of Last Dose: 06MAR2021

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1975	45	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
172.72 cm	81.91 kg	27.4 kg/m2	06AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Allergic Rhinitis-Seasonal	Seasonal allergy	1976	Present
Hair Loss	Alopecia	2000	Present
Umbilical hernia	Umbilical hernia	2010	Present
Pectoralis Tendon Tear-Right	Tendon rupture	2013	Past
Pectoralis tendon Tear Repair-Right	Tenoplasty	2013	Past
Partial Achilles Tendon Tear-Right Foot	Tendon rupture	MAR2018	Past
Right Foot Achilles Tendon Repair	Tenoplasty	MAR2018	Past
Stomach Cramps	Abdominal pain upper	03AUG2020	Present

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1083 10831060; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 06AUG2020; Date of Last Dose: 06MAR2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	06AUG2020 (1)	11:30
3	BNT162b2	06MAR2021 (213)	11:00

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Abdominal pain	Worsening of Abdominal Pain	14AUG2020 (9)	00:00	24AUG2020 (19)	11:32	11	4
2	INFEC	Cellulitis	Phlegmon Formation	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3
3	GASTR	Diverticular perforation	Ruptured diverticulum	14AUG2020 (9)	00:00	24AUG2020 (19)	00:00	11	4
4	INFEC	Diverticulitis	Diverticulitis	20AUG2020 (15)	00:00	25AUG2020 (20)		6	4
5	INFEC	Diverticulitis	Diverticulitis	26AUG2020 (21)		ONGOING			3
6	GENRL	Fatigue	Fatigue	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
7	NERV	Headache	Slight Headache	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
8	GENRL	Injection site pain	Injection Site Pain-Left	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
9	MUSC	Myalgia	Muscle Aches	07MAR2021 (214)	00:00	08MAR2021 (215)	00:00	2	1
10	INJ&P	Postoperative ileus	Post Operative Ileus	18AUG2020 (13)	00:00	23AUG2020 (18)	00:00	6	2
11	GASTR	Small intestinal obstruction	Small Bowel Obstruction	20AUG2020 (15)	00:00	20AUG2020 (15)	00:00	1	3

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1083 10831060; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 06AUG2020; Date of Last Dose: 06MAR2021

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (24AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	9	N
2	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Diverticulitis	1	15	N
3	TC/TCN/P	Y	Resolved (24AUG2020)	NOT RELATED/OTHER: Infection	1	9	Y
4	TC/TCN	N	Resolved (25AUG2020)	NOT RELATED/OTHER: Infection	1	15	N
5	TC	N	Yes	NOT RELATED/OTHER: Medical event	1	21	N
6	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
7	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
8	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
9	N	N	Resolved (08MAR2021)	Study Treatment	3	2	N
10	TC	N	Resolved (23AUG2020)	NOT RELATED/OTHER: Surgical Side Effect	1	13	N
11	TC/TCN	N	Resolved (20AUG2020)	NOT RELATED/OTHER: Ruptured Diverticulum	1	15	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza Vaccine	INFLUENZA VACCINE	02FEB2021

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1083 10831060; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 06AUG2020; Date of Last Dose: 06MAR2021

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	06AUG2020	
Withdrawn	VACCINATION	14AUG2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	06MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1083 10831060; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 06AUG2020; Date of Last Dose: 06MAR2021

Narrative Comment

Subject C4591001 1083 10831060, a 45-year-old white male with a pertinent medical history of upper abdominal pain (since 03 Aug 2020), received Dose 1 on 06 Aug 2020. The subject was diagnosed with a diverticular perforation on 14 Aug 2020, 8 days after receiving Dose 1.

Concomitant medications included finasteride (since Apr 2020) for hair loss, dicyclomine and omeprazole magnesium (since 11 Aug 2020) for stomach cramps, and acetaminophen (since 11 Aug 2020) for fever.

On 06 Aug 2020 (Day 1), the subject did not report any symptoms related to the diverticular perforation. On 08 Aug 2020 (Day 3), the subject had a fever, and on 11 Aug 2020 (Day 6), he experienced abdominal pain and reported both to the site. The subject was prescribed dicyclomine and omeprazole for possible gastritis by (b) (6) who was a family physician; additionally, the subject was also taking acetaminophen before the onset of the abdominal pain for fever. The subject stated that he had abdominal cramps since 03 Aug 2020 (Day -3); however, he did not report this to the clinical research coordinator at the time of screening. On 13 Aug 2020 (Day 8), the subject visited a primary care physician for a Helicobacter pylori test; the result was unknown. On 14 Aug 2020 (Day 9), the subject presented to the emergency department with worsening right-sided abdominal pain and was hospitalized ultimately for a small-bowel obstruction. He was diagnosed with a heterogeneous cecal mass via a computed tomogram of the abdomen/pelvis with contrast performed on the same day. On 15 Aug 2020 (Day 10), a SARS-CoV-2 test result was negative. On 16 Aug 2020 (Day 11), 4 benign lymph nodes, ruptured diverticulum, sessile serrated polyps/adenoma, focal serosal colon adhesions, and benign liver cyst were observed via an exploratory laparotomy. On the same day (Day 11), the subject underwent bowel resection with a right hemicolectomy and allograft tissue reinforcement of anastomosis and abdominal wall excision; the right colon and appendix were removed. The pathology result was negative for malignancy. On 17 Aug 2020 (Day 12), a magnetic resonance imaging scan with and without contrast confirmed the benign liver cyst. On 18 Aug 2020 (Day 13), the subject experienced postoperative ileus. On 20 Aug 2020 (Day 15), he was diagnosed with phlegmon formation, small-intestinal obstruction, and diverticulitis. The small-intestinal obstruction and phlegmon formation resolved on the same day (Day 15), and the subject was able to tolerate an oral diet without difficulties. On 23 Aug 2020 (Day 18), the postoperative ileus was considered resolved. On 24 Aug 2020 (Day 19), the subject's laboratory tests showed an elevated alanine aminotransferase of 114 IU/L (normal range [NR]: 16-61 IU/L) and elevated aspartate aminotransferase of 82 IU/L (NR: 15-37 IU/L). A culture was performed (date not provided), which was negative. The subject recovered from the diverticular perforation and worsening of abdominal pain on 24 Aug 2020 (Day 19). He was discharged from the hospital on the same day (Day 19) with the following medications: gabapentin 300 mg orally (PO) 3 times a day, docusate sodium 100 mg PO once daily, pantoprazole 40 mg PO every morning, sucralfate 1 g PO 4 times a day as needed, and tramadol 50 mg PO every 8 hours. The investigator considered the diverticular perforation as life-threatening. On 18 Sep 2020 (Day 44), the subject reported that he was not stable enough to travel or attend the safety visit.

The subject was discontinued from the study intervention on 14 Aug 2020 because of the diverticular perforation and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received a first dose of BNT162b2 on 06 Mar 2021 (Day 213) and remains in the study. The diverticulitis was ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the diverticular perforation was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to infection. Pfizer concurred with the investigator's causality assessment.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1091 10911197; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 28AUG2020; Date of Last Dose: 01MAR2021

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1966	54	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
181 cm	84.6 kg	25.8 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
seasonal allergies	Seasonal allergy	1976	Present
chest pain	Chest pain	2008	Past
cyst in esophagus	Oesophageal cyst	2008	Past
removal of esophageal cyst	Oesophageal lesion excision	2008	Past
DVT	Deep vein thrombosis	2017	Past
restless leg syndrome	Restless legs syndrome	2017	Present
depression	Depression	OCT2019	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1091 10911197; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 28AUG2020; Date of Last Dose: 01MAR2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	11:43
2	Placebo	17SEP2020 (21)	10:02
3	BNT162b2	01MAR2021 (186)	08:23

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GASTR	Diarrhoea	Diarrhea	17SEP2020 (21)		03OCT2020 (37)		17	1
2	RESP	Hypoxia	hypoxia	26SEP2020 (30)		27SEP2020 (31)		2	3
3	RESP	Nasal congestion	nasal congestion	10OCT2020 (44)		17OCT2020 (51)	10:00	8	1
4	RESP	Pneumonia aspiration	Aspiration Pneumonia	26SEP2020 (30)		06OCT2020 (40)		11	3
5	INJ&P	Toxicity to various agents	poisoning by cocaine	26SEP2020 (30)		27SEP2020 (31)		2	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (03OCT2020)	Study Treatment	2	1	N
2	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: opioid overdose	2	10	Y
3	N	N	Resolved (17OCT2020)	NOT RELATED/OTHER: environmental irritant	2	24	N
4	TC	Y	Resolved (06OCT2020)	NOT RELATED/OTHER: poisoning by cocaine	2	10	Y
5	TC/TCN	Y	Resolved (27SEP2020)	NOT RELATED/OTHER: substance abuse	2	10	Y

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1091 10911197; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 28AUG2020; Date of Last Dose: 01MAR2021

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	01MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1091 10911300; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 15SEP2020; Date of Last Dose: 06OCT2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
162.3 cm	87.5 kg	33.2 kg/m2	15SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
broken jaw repair surgery	Fracture treatment	1992	Past
Broken jaw	Jaw fracture	1992	Past
occasional migraines	Migraine	1995	Present
allergic rhinitis	Rhinitis allergic	2000	Present
Bilateral carpal tunnel syndrome	Carpal tunnel syndrome	2005	Past
Bilateral carpal tunnel release	Carpal tunnel decompression	2011	Past
menorrhagia	Menorrhagia	2015	Past
Reduction Mammoplasty (breast reduction)	Mammoplasty	DEC2018	Past
endometrial ablation	Endometrial ablation	DEC2019	Past

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1091 10911300; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 15SEP2020; Date of Last Dose: 06OCT2020

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	15SEP2020 (1)	10:48
2	BNT162b2	06OCT2020 (22)	09:32

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	INFECTION	Appendicitis	Appendicitis	21OCT2020 (37)		22OCT2020 (38)	05:55	2	4	TCN
2	GENRL	Chills	Chills	06OCT2020 (22)	21:30	07OCT2020 (23)	08:00	2	1	N
3	GENRL	Injection site pain	Injection Site Pain	06OCT2020 (22)	13:00	07OCT2020 (23)		2	1	N
4	GENRL	Injection site pain	soreness at injection site	16SEP2020 (2)		17SEP2020 (3)		2	1	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (22OCT2020)	NOT RELATED/OTHER: Inflammation of Appendix, Unknown Cause	2	16	Y
2	N	Resolved (07OCT2020)	Study Treatment	2	1	N
3	N	Resolved (07OCT2020)	Study Treatment	2	1	N
4	N	Resolved (17SEP2020)	Study Treatment	1	2	N

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1091 10911300; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 15SEP2020; Date of Last Dose: 06OCT2020

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
influenza vaccine	INFLUENZA VACCINE	27OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	15SEP2020	
Completed	VACCINATION	06NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1091 10911300; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 15SEP2020; Date of Last Dose: 06OCT2020

Narrative Comment

Subject C4591001 1091 10911300, a 46-year-old white female with a pertinent medical history of endometrial ablation (in Dec 2019), received Dose 1 on 15 Sep 2020 and Dose 2 on 06 Oct 2020 (Day 22). The subject was diagnosed with appendicitis on 21 Oct 2020, 15 days after receiving Dose 2. Concomitant medications included cetirizine (since 2000) for allergic rhinitis and paracetamol (on 06 Oct 2020) for chills. On 21 Oct 2020 (Day 37), the subject experienced a rapid onset of right-sided lower abdominal pain and went to the emergency room. On 22 Oct 2020 (Day 38), a computed tomography scan of the abdomen and pelvis showed acute appendicitis without evidence of collection or perforation and scattered colonic diverticula without inflammatory changes. Laboratory tests showed a white blood cell count of $15 \times 10^3/\text{mm}^3$ (normal range [NR]: $4.0\text{-}10.5 \times 10^3/\text{mm}^3$), absolute neutrophils of $10.3 \times 10^3/\text{mm}^3$ (NR: $2.0\text{-}7.3 \times 10^3/\text{mm}^3$), and alanine aminotransferase of 58 U/µL (NR: 7-52 U/µL). The subject was not hospitalized, as all the hospital beds were full at the facility. She underwent a laparoscopic appendectomy without any complications and was discharged from the operating room with prescriptions for docusate and oxycodone/acetaminophen. Pathologic examination of the appendix revealed adhesions in attached portion of pink-yellow adipose tissue measuring $4.5 \times 2.0 \times 1.8$ cm; staple line on the proximal margin. Sectioning of the appendix revealed hemorrhagic red-gray cut surface with the lumen diameter measuring to 0.4 cm and a wall thickness measuring up to 0.3 cm. On 22 Oct 2020 (Day 38), the appendicitis resolved. The appendicitis was considered medically significant by the investigator. In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1095 10951173; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 29AUG2020; Date of Last Dose: 04FEB2021

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1971	49	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
167 cm	87.5 kg	31.4 kg/m2	29AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
seasonal allergies	Seasonal allergy	2006	Present
vasectomy	Vasectomy	2014	Past

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1095 10951173; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 29AUG2020; Date of Last Dose: 04FEB2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	29AUG2020 (1)	15:16
UNPLANNED	BNT162b2	04FEB2021 (160)	11:01

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Acute myocardial infarction	STEMI: ST elevation Myocardial Infarction	05SEP2020 (8)		09SEP2020 (12)		5	4
2	CARD	Coronary artery disease	Coronary Artery Disease	05SEP2020 (8)		ONGOING			2

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC/TCN	Y	Resolved (09SEP2020)	NOT RELATED/OTHER: undiagnosed Obstructive CAD	1	8	Y
2	TC	N	Yes	NOT RELATED/OTHER: CAD	1	8	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1095 10951173; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 29AUG2020; Date of Last Dose: 04FEB2021

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Influenza vaccine 1 dose IM once for influenza prevention	INFLUENZA VACCINE	28OCT2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	29AUG2020	
	VACCINATION		
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1109 11091204; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 04SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1992	27	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
182.88 cm	90.91 kg	27.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
RECONSTRUCTIVE RIGHT EAR SURGERY	Otoplasty	01JAN2013	Past
SEASONAL ALLERGIES	Seasonal allergy	2015	Present
BILATERAL LASIK SURGERY	Keratomileusis	01JAN2015	Past

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1109 11091204; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 04SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	11AUG2020 (1)	13:15
2	BNT162b2	04SEP2020 (25)	14:18

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	INFECTION	Appendicitis	ACUTE APPENDICITIS	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y
2	INFECTION	Peritoneal abscess	Peritoneal Abscess	17AUG2020 (7)		02SEP2020 (23)		17	4	TC	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (02SEP2020)	NOT RELATED/OTHER: ACUTE APPENDICITIS WITH PERITONEAL ABSCESS	1	7	Y
2	Resolved (02SEP2020)	NOT RELATED/OTHER: Acute appendicitis with peritoneal abscess	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1109 11091204; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 04SEP2020

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Completed	VACCINATION	30SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Appendicitis

Unique Subject ID: C4591001 1109 11091204; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 04SEP2020

Narrative Comment

Subject C4591001 1109 11091204, a 27-year-old white male with no pertinent medical history, received Dose 1 on 11 Aug 2020 and Dose 2 on 04 Sep 2020 (Day 25). The subject was diagnosed with acute appendicitis and a peritoneal abscess on 17 Aug 2020, 6 days after receiving Dose 1.

Concomitant medication included cetirizine hydrochloride (dates not reported) for allergies.

On 17 Aug 2020 (Day 7), the subject was hospitalized for abdominal pain and diagnosed with acute appendicitis and a peritoneal abscess. He was treated with piperacillin/tazobactam 2.25 g intravenous piggyback every 6 hours (from 17 Aug 2020 to 22 Aug 2020) and acetaminophen/oxycodone 325/5 mg (from 21 Aug 2020 to 22 Aug 2020) for pain. Appendectomy was not indicated. A SARS-CoV-2 test was not performed. The subject was discharged from the hospital on 21 Aug 2020 (Day 11) on ciprofloxacin and metronidazole (from 22 Aug 2020 to 25 Aug 2020); he was treated with amoxicillin 500 mg orally twice a day (from 26 Aug 2020 to 02 Sep 2020). The acute appendicitis with peritoneal abscess resolved on 02 Sep 2020 (Day 23). The subject was instructed to delay the second dose of study vaccination until completion of antibiotic treatment.

In the opinion of the investigator, there was no reasonable possibility that the acute appendicitis and peritoneal abscess were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1109 11091448; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 08SEP2020; Date of Last Dose: 28SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1974	46	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
167.64 cm	82.73 kg	29.4 kg/m2	08SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
FIBROMYALGIA	Fibromyalgia	1990	Present
ALLERGY TO KEFLEX	Drug hypersensitivity	1995	Present
ALLERGY TO AUGMENTIN	Drug hypersensitivity	1995	Present
ALLERGY TO BIAVIN	Drug hypersensitivity	2005	Present
ALLERGY TO LATEX	Rubber sensitivity	2005	Present
HYSTERECTOMY	Hysterectomy	2006	Past
POSTMENOPAUSAL	Postmenopause	2006	Present
ALLERGY TO SEPTRA	Drug hypersensitivity	2008	Present

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1109 11091448; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 08SEP2020; Date of Last Dose: 28SEP2020

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Headaches	Headache	2010	Present
Hemiplegic Migraine	Hemiplegic migraine	2010	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	08SEP2020 (1)	15:07
2	Placebo	28SEP2020 (21)	08:50

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	NERV	Hemiplegic migraine	Hemiplegic Migraine	20OCT2020 (43)		ONGOING			4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Yes	NOT RELATED/OTHER: Related to subjects history of headaches	2	23	Y

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1109 11091448; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 08SEP2020; Date of Last Dose: 28SEP2020

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Completed	VACCINATION	28OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1117 11171036; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 20AUG2020; Date of Last Dose: 10SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1974	45	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
194.56 cm	122.36 kg	32.3 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
FISH ALLERGY	Food allergy	1979	Present
ALCOHOLISM	Alcoholism	2005	Past
BIPOLAR DISORDER	Bipolar disorder	2016	Present
HYPERTENSION	Hypertension	2016	Present
MAJOR DEPRESSIVE DISORDER	Major depression	2016	Present
SCHIZOPHRENIA	Schizophrenia	2016	Present
ANXIETY	Anxiety	2017	Present
INSOMNIA	Insomnia	2017	Present
CONSTIPATION	Constipation	2018	Present

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1117 11171036; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 20AUG2020; Date of Last Dose: 10SEP2020

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
DIABETES MELLITUS TYPE II	Type 2 diabetes mellitus	2019	Present
Chronic Kidney Disease, Stage 2	Chronic kidney disease	JAN2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	20AUG2020 (1)	16:02
2	Placebo	10SEP2020 (22)	13:12

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	RENAL	Acute kidney injury	ACUTE KIDNEY INJURY	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
2	RENAL	Chronic kidney disease	CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING	31DEC2020 (134)		ONGOING			2	N	N
3	METAB	Diabetes mellitus	WORSENING DIABETES MELLITUS TYPE 2	10NOV2020 (83)		ONGOING			2	TC	N
4	VASC	Hypertension	WORSENING HYPERTENSION	SEP2020 ()		ONGOING			2	TC	N
5	METAB	Hypocalcaemia	HYPOCALCEMIA	SEP2020 ()		ONGOING			2	TC	N
6	PSYCH	Insomnia	WORSENING INSOMNIA	SEP2020 ()		ONGOING			2	N	N

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File: /nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1117 11171036; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 20AUG2020; Date of Last Dose: 10SEP2020

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
7	PSYCH	Major depression	MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	30DEC2020 (133)		01JAN2021 (135)		3	3	TC/TCN	Y
8	MUSC	Musculoskeletal stiffness	NECK STIFFNESS	21SEP2020 (33)	08:00	24OCT2020 (66)		34	1	N	N
9	MUSC	Pain in extremity	ARM SORENESS, LEFT	22SEP2020 (34)	08:00	02OCT2020 (44)		11	2	N	N
10	MUSC	Rhabdomyolysis	RHABDOMYOLYSIS	26AUG2020 (7)		30AUG2020 (11)		5	1	TC	N
11	RESP	Snoring	SNORING	SEP2020 ()		ONGOING			2	N	N
12	PSYCH	Suicidal ideation	SUICIDAL IDEATION	20NOV2020 (93)		25NOV2020 (98)		6	4	TC/TCN	Y
13	PSYCH	Suicidal ideation	Suicidal ideation	27AUG2020 (8)		30AUG2020 (11)		4	4	TC	Y
14	NERV	Syncope	Syncopal Episode	26AUG2020 (7)		30AUG2020 (11)		5	4	N	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
2	Yes	NOT RELATED/OTHER: DIABETES MELLITUS II DISEASE PROGRESSION	2	113	N
3	Yes	NOT RELATED/OTHER: DISEASE PROGRESSION	2	62	N
4	Yes	NOT RELATED/OTHER: NON COMPLIANCE WITH PLAN OF CARE			N

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: /nda2_unblinded/C4591001_BLA_Narrative_Other_AEI_SAE/profile Date of Generation: 07APR2021 (21:52)

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1117 11171036; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 20AUG2020; Date of Last Dose: 10SEP2020

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
5	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
6	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
7	Resolved (01JAN2021)	NOT RELATED/OTHER: BIPOLAR DISORDER	2	112	Y
8	Resolved (24OCT2020)	NOT RELATED/OTHER: ETIOLOGY UNKNOWN PER INVESTIGATOR	2	12	N
9	Resolved (02OCT2020)	NOT RELATED/OTHER: ETIOLOGY NOT KNOWN PER INVESTIGATOR	2	13	N
10	Resolved (30AUG2020)	NOT RELATED/OTHER: HEAT RELATED EVENT	1	7	N
11	Yes	NOT RELATED/OTHER: ETIOLOGY UNKNOWN			N
12	Resolved (25NOV2020)	NOT RELATED/OTHER: MENTAL HEALTH DISORDER	2	72	Y
13	Resolved (30AUG2020)	NOT RELATED/OTHER: Per participant: "due to being in the hospital"	1	8	Y
14	Resolved (30AUG2020)	NOT RELATED/OTHER: Due to heat, acute kidney injury, rhabdomyolysis	1	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1117 11171036; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 20AUG2020; Date of Last Dose: 10SEP2020

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Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
INFLUENZA VACCINE	INFLUENZA VACCINE	14SEP2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	08OCT2020	
Withdrawn	REPEAT SCREENING 1	28JAN2021	NO LONGER MEETS ELIGIBILITY CRITERIA
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1124 11241106; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 26AUG2020; Date of Last Dose: 16SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1971	48	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
180.34 cm	86.36 kg	26.5 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
High Cholesterol	Blood cholesterol increased	2001	Present
Vasectomy	Vasectomy	2001	Past
Gastroesophageal reflux disease	Gastroesophageal reflux disease	2004	Present
Lower back pain	Back pain	2009	Present

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1124 11241106; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 26AUG2020; Date of Last Dose: 16SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	26AUG2020 (1)	14:53
2	BNT162b2	16SEP2020 (22)	08:58

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	CARD	Acute myocardial infarction	ST elevation myocardial infarction	27SEP2020 (33)		13OCT2020 (49)		17	4	N
2	INJ&P	Fall	Fall from Bicycle	27SEP2020 (33)		27SEP2020 (33)		1	2	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (13OCT2020)	NOT RELATED/OTHER: related to cardiovascular risk	2	12	Y
2	N	Resolved (27SEP2020)	NOT RELATED/OTHER: Due to SAE of Myocardial Infarction	2	12	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001

Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1124 11241106; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 26AUG2020; Date of Last Dose: 16SEP2020

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Completed	VACCINATION	15OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Anaphylaxis

Unique Subject ID: C4591001 1140 11401009; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 31JUL2020; Date of Last Dose: 20AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1979	40	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
183.79 cm	102.09 kg	30.2 kg/m2	31JUL2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Asthma	Asthma	01NOV1985	Present
Allergy to cats	Allergy to animal	01AUG1988	Present
Allergy to bees	Allergy to arthropod sting	01AUG1988	Present
allergy to penicillin	Drug hypersensitivity	01AUG1988	Present
Allergy to shrimp	Food allergy	01AUG1988	Present
Gout	Gout	01SEP2013	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Anaphylaxis

Unique Subject ID: C4591001 1140 11401009; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 31JUL2020; Date of Last Dose: 20AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	31JUL2020 (1)	09:28
2	BNT162b2	20AUG2020 (21)	14:57

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	IMMUN	Anaphylactic reaction	Anaphylaxis Status Post Bee Sting	28AUG2020 (29)	14:00	28AUG2020 (29)	20:00	1	4	TC
2	INFEC	Infected bite	Cellulitis Status Post Bee Sting	30AUG2020 (31)	08:00	09SEP2020 (41)	08:00	11	2	TC
3	GENRL	Injection site pain	Injection Site Pain	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	1	N
4	GENRL	Injection site swelling	Injection Site Swelling	31JUL2020 (1)	12:00	01AUG2020 (2)	08:00	2	2	N

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Y	Resolved (28AUG2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	9	Y
2	N	Resolved (09SEP2020)	NOT RELATED/OTHER: Subject with history of allergy to bee venom	2	11	N
3	N	Resolved (01AUG2020)	Study Treatment	1	1	N
4	N	Resolved (01AUG2020)	Study Treatment	1	1	N

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Anaphylaxis

Unique Subject ID: C4591001 1140 11401009; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 31JUL2020; Date of Last Dose: 20AUG2020

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31JUL2020	
Completed	VACCINATION	17SEP2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Anaphylaxis

Unique Subject ID: C4591001 1140 11401009; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 31JUL2020; Date of Last Dose: 20AUG2020

Narrative Comment

Subject C4591001 1140 11401009, a 40-year-old white male with a pertinent medical history of asthma (since 01 Nov 1985) and multiple allergies, including to animals (cats) and arthropod stings (bees), drug hypersensitivity (penicillin), and food allergy (shrimp) (all since 01 Aug 1988), received Dose 1 on 31 Jul 2020 and Dose 2 on 20 Aug 2020 (Day 21). The subject was diagnosed with an anaphylactic reaction on 28 Aug 2020, 8 days after receiving Dose 2.

Concomitant medications included salbutamol sulfate (since 01 Nov 1985) for asthma, montelukast sodium (since 01 Sep 2014) for asthma, and allopurinol (since 01 Sep 2014) for gout.

On 17 Sep 2020, during his follow-up visit, the subject reported that he was stung by a bee on his second right toe on 28 Aug 2020 (Day 29), which resulted in a visit to the emergency department (ED). He initially attempted to treat the sting by applying ice and taking diphenhydramine. However, he developed a high-pitched voice and his epinephrine medication at home was expired. He was subsequently taken to the ED for anaphylaxis treatment. The anaphylactic reaction was considered life-threatening. While in the ED, the subject was noted to have stridor and was treated with epinephrine, famotidine, and methylprednisolone sodium succinate. His condition improved after treatment and the anaphylactic reaction resolved on the same day (Day 29), which resulted in the subject being discharged from the ED.

On 30 Aug 2020 (Day 31), the subject developed an infected bite (cellulitis secondary to bee sting) and was treated with Keflex. No relevant tests were reported. On 09 Sep 2020 (Day 41), the infected bite resolved.

In the opinion of the investigator, there was no reasonable possibility that the anaphylactic reaction was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to a history of allergy to bee venom. Pfizer concurred with the investigator's causality assessment.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1141 11411153; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 31AUG2020; Date of Last Dose: 02MAR2021

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1978	41	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
164.1 cm	53.2 kg	19.8 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
spinal fusion	Spinal fusion surgery	1992	Past
spine surgery	Spinal operation	JUN1992	Past
chronic back pain	Back pain	2002	Present
scoliosis	Scoliosis	2002	Present
spondylolisthesis	Spondylolisthesis	2002	Present
spine surgery	Spinal operation	AUG2004	Past
spine surgery	Spinal operation	DEC2005	Past
spine surgery	Spinal operation	MAY2010	Past
migraines	Migraine	2012	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1141 11411153; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 31AUG2020; Date of Last Dose: 02MAR2021

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
anxiety	Anxiety	2015	Present
depression	Depression	2015	Present
Failed back surgical syndrome	Post laminectomy syndrome	OCT2016	Present
spinal cord stimulator bilateral implantation	Spinal nerve stimulator implantation	OCT2016	Past
spinal neurostimulator lead bilateral insertion	Spinal nerve stimulator implantation	10FEB2017	Past
removal of spinal cord stimulator	Medical device removal	21JUN2019	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	31AUG2020 (1)	13:15
2	Placebo	21SEP2020 (22)	11:36
3	BNT162b2	09FEB2021 (163)	15:01
4	BNT162b2	02MAR2021 (184)	12:32

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
1	NERV	Dizziness	Dizziness	14JAN2021 (137)		29JAN2021 (152)		16	2	N
2	NERV	Dizziness	Dizziness	15FEB2021 (169)		25FEB2021 (179)		11	3	N
3	NERV	Dizziness	Lightheadedness	02OCT2020 (33)	19:00	ONGOING			3	TC
4	NERV	Dizziness	Lightheadedness	14JAN2021 (137)		29JAN2021 (152)		16	2	N

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1141 11411153; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 31AUG2020; Date of Last Dose: 02MAR2021

Adverse Events										
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject
5	GENRL	Fatigue	Fatigue	15FEB2021 (169)		25FEB2021 (179)		11	3	N
6	NERV	Headache	Headache	14JAN2021 (137)		29JAN2021 (152)		16	3	N
7	NERV	Headache	Headache	15FEB2021 (169)		25FEB2021 (179)		11	3	N
8	CARD	Junctional ectopic tachycardia	Junctional ectopic tachycardia	02OCT2020 (33)		06JAN2021 (129)		97	4	TC/TCN
9	NERV	Presyncope	Near syncopal episode	2021 ()		ONGOING			2	N
10	CARD	Tachycardia	Tachycardia	03OCT2020 (34)		ONGOING			3	TC
11	CARD	Tachycardia	Tachycardia	13JAN2021 (136)		ONGOING			2	TC

Adverse Events						
AE Number	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
2	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
3	N	Yes	NOT RELATED/OTHER: supraventricular tachycardia	2	12	N
4	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
5	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
6	N	Resolved (29JAN2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	116	N
7	N	Resolved (25FEB2021)	NOT RELATED/CONCOMITANT DRUG TREATMENT	3	7	N
8	Y	Resolved (06JAN2021)	NOT RELATED/OTHER: Aberrant cardiac ectopic rhythm locus	2	12	Y
9	N	Yes	NOT RELATED/OTHER: likely related to patient's tachycardia			N
10	N	Yes	NOT RELATED/OTHER: supraventricular tachycardia	2	13	N
11	N	Yes	NOT RELATED/OTHER: sinus tachycardia	2	115	N

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1141 11411153; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 31AUG2020; Date of Last Dose: 02MAR2021

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Completed	VACCINATION	19OCT2020	
Completed	REPEAT SCREENING 1	09FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1142 11421084; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 12AUG2020; Date of Last Dose: 04SEP2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
170.18 cm	82 kg	28.3 kg/m2	12AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Major Depressive Disorder	Major depression	2018	Present
Schizophrenia	Schizophrenia	2018	Present

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1142 11421084; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 12AUG2020; Date of Last Dose: 04SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12AUG2020 (1)	13:41
2	Placebo	04SEP2020 (24)	15:20

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INJ&P	Craniocerebral injury	Closed head injury	19AUG2020 (8)		19AUG2020 (8)		1	3
2	PSYCH	Suicidal ideation	Suicidal Ideation	19AUG2020 (8)		21AUG2020 (10)		3	4

Adverse Events								
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event	
1	N	N	Resolved (19AUG2020)	NOT RELATED/OTHER: Subject was in "an altercation"	1	8	N	
2	TC	Y	Resolved (21AUG2020)	NOT RELATED/OTHER: History of Major Depressive Disorder	1	8	Y	

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1142 11421084; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 12AUG2020; Date of Last Dose: 04SEP2020

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	12AUG2020	
Withdrawn	VACCINATION	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	04NOV2020	NO LONGER MEETS ELIGIBILITY CRITERIA

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1218 12181057; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 08DEC2020; Date of Last Dose: 08MAR2021

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1989	31	American Indian or Alaska Native	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
187.5 cm	128.2 kg	36.5 kg/m2	08DEC2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Obesity	Obesity	07MAR2009	Present
Seizures	Seizure	20NOV2014	Past
Alcoholic Hepatitis	Hepatitis alcoholic	MAY2020	Past
Alcoholic cirrhosis	Cirrhosis alcoholic	JUN2020	Present
Acute renal failure secondary to hepatorenal syndrome	Hepatorenal syndrome	16JUN2020	Past
Type 2 Diabetes	Type 2 diabetes mellitus	15OCT2020	Present

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1218 12181057; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 08DEC2020; Date of Last Dose: 08MAR2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	08DEC2020 (1)	13:16
3	BNT162b2	16FEB2021 (71)	11:02
4	BNT162b2	08MAR2021 (91)	09:49

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	GENRL	Injection site pain	Injection site pain	08DEC2020 (1)	13:16	09DEC2020 (2)	17:07	2	1
2	GASTR	Oesophageal varices haemorrhage	Esophageal varices hemorrhage	09JAN2021 (33)		09JAN2021 (33)		1	4
3	GASTR	Toothache	Toothache	01FEB2021 (56)		04FEB2021 (59)		4	1
4	GASTR	Vomiting	Vomiting	09DEC2020 (2)	08:00	09DEC2020 (2)	14:00	1	1

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	N	N	Resolved (09DEC2020)	Study Treatment	1	1	N
2	TC/TCN	Y	Resolved (09JAN2021)	NOT RELATED/OTHER: Decompensated alcoholic cirrhosis	1	33	Y
3	TC/TCN	N	Resolved (04FEB2021)	NOT RELATED/OTHER: Dental caries	1	56	N
4	N	N	Resolved (09DEC2020)	Study Treatment	1	2	N

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1218 12181057; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 08DEC2020; Date of Last Dose: 08MAR2021

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08DEC2020	
Withdrawn	VACCINATION	22JAN2021	OTHER
Completed	REPEAT SCREENING 1	16FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1226 12261300; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 20AUG2020; Date of Last Dose: 11SEP2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
175 cm	92.3 kg	30.1 kg/m2	20AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
obesity	Obesity	2000	Present
Vasectomy	Vasectomy	2015	Past
renal lithiasis	Nephrolithiasis	APR2020	Present

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1226 12261300; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 20AUG2020; Date of Last Dose: 11SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	20AUG2020 (1)	09:39
2	BNT162b2	11SEP2020 (23)	08:44

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	INFEC	Conjunctivitis	Conjunctivitis	01SEP2020 (13)		07SEP2020 (19)		7	1
2	RENAL	Renal colic	Renal colic	29AUG2020 (10)	05:00	30AUG2020 (11)	12:00	2	4

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	N	Resolved (07SEP2020)	NOT RELATED/OTHER: possible cause: bacterial	1	13	N
2	TC/TCN	Y	Resolved (30AUG2020)	NOT RELATED/OTHER: Renal lithiasis	1	10	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1226 12261300; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 20AUG2020; Date of Last Dose: 11SEP2020

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	20AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1231 12312854; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 21AUG2020; Date of Last Dose: 11SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1976	44	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
172 cm	149 kg	50.4 kg/m2	21AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Sleep apnea	Sleep apnoea syndrome	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	21AUG2020 (1)	13:20
2	BNT162b2	11SEP2020 (22)	10:50

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1231 12312854; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 21AUG2020; Date of Last Dose: 11SEP2020

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Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	CARD	Arrhythmia supraventricular	Arrhythmia supraventricular	17SEP2020 (28)	11:00	19SEP2020 (30)	10:00	3	4	TC/TCN	Y

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (19SEP2020)	NOT RELATED/OTHER: unknown, but probably corresponds to an accessory intraventricular line	2	7	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001

Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1231 12312854; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 21AUG2020; Date of Last Dose: 11SEP2020

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	21AUG2020	
Completed	VACCINATION	09OCT2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1251 12511239; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 13OCT2020; Date of Last Dose: 02NOV2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1972	48	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
165.1 cm	119.55 kg	43.8 kg/m2	13OCT2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Allergies Seasonal	Seasonal allergy	1980	Present
Obesity	Obesity	1990	Present
Tubal Ligation	Female sterilisation	1993	Past
Schizophrenia	Schizophrenia	2005	Present
Depression	Depression	2006	Present
Hypertension	Hypertension	2010	Present
Hysterectomy Partial	Hysterectomy	2010	Past
Heavy Menstrual Bleeding	Menorrhagia	2010	Past
Diabetes Mellitus Type II	Type 2 diabetes mellitus	2010	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1251 12511239; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 13OCT2020; Date of Last Dose: 02NOV2020

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Cholecystectomy	Cholecystectomy	2011	Past
Cholecystitis	Cholecystitis	2011	Past
Hypercholesterolemia	Hypercholesterolaemia	2014	Present
Diabetic Neuropathy	Diabetic neuropathy	21NOV2014	Present
Postmenopausal	Postmenopause	2015	Present
Knee Pain B/L	Arthralgia	2017	Present
Sulfa Allergy	Drug hypersensitivity	2017	Present
Osteoarthritis Knee Bilateral	Osteoarthritis	2017	Present
Congestive Heart Failure	Cardiac failure congestive	2018	Present
Fluid Retention	Fluid retention	2018	Present
chest pain	Chest pain	AUG2020	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	13OCT2020 (1)	12:00
2	BNT162b2	02NOV2020 (21)	11:05

Adverse Events									
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade
1	CARD	Myocardial ischaemia	Myocardial ischemia	13NOV2020 (32)		16NOV2020 (35)		4	4

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Reason(s) for Narrative: Other SAE

Unique Subject ID: C4591001 1251 12511239; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 13OCT2020; Date of Last Dose: 02NOV2020

Adverse Events							
AE Number	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	TC	Y	Resolved (16NOV2020)	NOT RELATED/OTHER: Congestive Heart Failure	2	12	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	13OCT2020	
Completed	VACCINATION	30NOV2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1012 10121163; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 09SEP2020; Date of Last Dose: 09SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1979	41	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
175.26 cm	63.18 kg	20.5 kg/m2	09SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Cat Scratch Disease	Cat scratch disease	1982	Present
Penicillin Allergy (Anaphylactic Shock)	Anaphylactic shock	1984	Present
Codeine Allergy	Drug hypersensitivity	1984	Present
Allergic Atopic Dermatitis	Dermatitis atopic	2016	Present
Iodine Allergy	Iodine allergy	2017	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1012 10121163; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 09SEP2020; Date of Last Dose: 09SEP2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	09SEP2020 (1)	16:58

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site dermatitis	LEFT UPPER ARM DERMATITIS AT INJECTION SITE	11SEP2020 (3)		ONGOING	
2	PSYCH	Insomnia	INSOMNIA	12SEP2020 (4)		ONGOING	
3	INV	Weight decreased	WEIGHT LOSS	14SEP2020 (6)		04OCT2020 (26)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1		2	P/W	N	Yes	Study Treatment	1	3	Y
2		2	TC	N	Yes	Study Treatment	1	4	N
3	21	3	N	N	Resolved (04OCT2020)	Study Treatment	1	6	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

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Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1012 10121163; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 09SEP2020; Date of Last Dose: 09SEP2020

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Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	09SEP2020	
Withdrawn	VACCINATION	24SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17OCT2020	ADVERSE EVENT

Narrative Comment
<p>Subject C4591001 1012 10121163, a 41-year-old white female with a pertinent medical history of atopic dermatitis (since 2016), received Dose 1 on 09 Sep 2020. The subject experienced injection site dermatitis (left upper arm) on 11 Sep 2020, 2 days after receiving Dose 1.</p> <p>The subject was discontinued from the study intervention on 24 Sep 2020, and was subsequently withdrawn from the study on 17 Oct 2020 because of injection site dermatitis.</p> <p>The injection site dermatitis was ongoing at the time of withdrawal.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the injection site dermatitis was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1015 10151134; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 27AUG2020; Date of Last Dose: 13JAN2021

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1965	55	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
182.88 cm	75 kg	22.4 kg/m2	27AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Childhood asthma	Childhood asthma	1975	Present
Acid reflux	Gastroesophageal reflux disease	2000	Present
Vertigo	Vertigo	2012	Present

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1015 10151134; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 27AUG2020; Date of Last Dose: 13JAN2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	27AUG2020 (1)	14:39
3	BNT162b2	21DEC2020 (117)	13:20
4	BNT162b2	13JAN2021 (140)	12:45

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Chills	Chills	13JAN2021 (140)	20:00	15JAN2021 (142)	
2	GASTR	Diarrhoea	Diarrhea	28AUG2020 (2)		28AUG2020 (2)	
3	NERV	Headache	Headache	28AUG2020 (2)		01SEP2020 (6)	
4	NERV	Headache	Headache	14JAN2021 (141)	03:00	15JAN2021 (142)	
5	GENRL	Injection site pain	Injection site pain	21DEC2020 (117)		22DEC2020 (118)	
6	GENRL	Injection site pain	Injection site pain	13JAN2021 (140)	20:00	15JAN2021 (142)	
7	GASTR	Nausea	Nausea	28AUG2020 (2)		01SEP2020 (6)	
8	EAR	Vertigo	Worsening and continuing episode of Vertigo	28AUG2020 (2)		21DEC2020 (117)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	3	1	N	N	Resolved (15JAN2021)	Study Treatment	4	1	N
2	1	1	N	N	Resolved (28AUG2020)	Study Treatment	1	2	N
3	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1015 10151134; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 27AUG2020; Date of Last Dose: 13JAN2021

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	2	2	TC	N	Resolved (15JAN2021)	Study Treatment	4	2	N
5	2	1	N	N	Resolved (22DEC2020)	Study Treatment	3	1	N
6	3	1	N	N	Resolved (15JAN2021)	Study Treatment	4	1	N
7	5	1	N	N	Resolved (01SEP2020)	Study Treatment	1	2	N
8	116	2	P	N	Resolved (21DEC2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
Fluzone Quadrivalent	INFLUENZA VACCINE INACT SPLIT 4V	28SEP2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	27AUG2020	

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1015 10151134; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 27AUG2020; Date of Last Dose: 13JAN2021

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Withdrawn	VACCINATION	06NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	21DEC2020	
Completed	OPEN LABEL TREATMENT	10FEB2021	
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1015 10151134, a 55-year-old white male with a pertinent medical history of vertigo (since 2012), received Dose 1 on 27 Aug 2020. The subject experienced a worsening and continuing episode of vertigo on 28 Aug 2020, 1 day after receiving Dose 1.</p> <p>On 28 Aug 2020 (Day 2), the subject also experienced diarrhea, headache, and nausea. The diarrhea resolved on the same day (Day 2) and the headache and nausea resolved on 01 Sep 2020 (Day 6). The subject received the influenza vaccine inact split 4V on 28 Sep 2020 (Day 33).</p> <p>The subject was discontinued from the study intervention on 06 Nov 2020 because of the worsening and continuing episode of vertigo. On 21 Dec 2020 (Day 117), the worsening and continuing episode of vertigo resolved.</p> <p>In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether he was eligible for receipt of BNT162b2. It was confirmed that he had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 21 Dec 2020 (Day 117) and 13 Jan 2021 (Day 140), respectively, and remains in the study.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the worsening and continuing episode of vertigo was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1016 10161087; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 10AUG2020; Date of Last Dose: 10AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1976	43	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
177.8 cm	77.32 kg	24.4 kg/m2	10AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
seasonal allergies	Seasonal allergy	APR1994	Present
allergy to flagyl	Drug hypersensitivity	APR2002	Present
meniscus repair	Meniscus operation	JUL2009	Past
migraines	Migraine	APR2010	Present
ovarian fibroid	Ovarian fibroma	JAN2015	Past
hysterectomy	Hysterectomy	JUN2015	Past

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Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1016 10161087; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 10AUG2020; Date of Last Dose: 10AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	10AUG2020 (1)	10:35

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site swelling	injection site swelling	10AUG2020 (1)		19AUG2020 (10)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	10	3	TC/P	N	Resolved (19AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1016 10161087; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 10AUG2020; Date of Last Dose: 10AUG2020

Nonstudy Vaccines		
Investigator Text	WHO Drug Preferred Term	Start Date
pfizer bnt162b2 vaccine	BNT162B2	14JAN2021

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	10AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1016 10161087, a 43-year-old white female with no pertinent medical history, received Dose 1 on 10 Aug 2020. On the same day (Day 1), the subject reported severe injection site swelling after receiving Dose 1.</p> <p>The injection site swelling resolved on 19 Aug 2020 (Day 10).</p> <p>The subject was discontinued from the study intervention on 31 Aug 2020 because of the injection site swelling and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the injection site swelling was related to the study intervention.</p>

Compound: PF-07302048; **Protocol:** C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1016 10161087; **Country:** USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 10AUG2020; **Date of Last Dose:** 10AUG2020

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Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1027 10271105; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 28AUG2020; Date of Last Dose: 28AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1974	46	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
164.47 cm	65.45 kg	24.1 kg/m2	28AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Migraine Headaches	Migraine	1995	Present
Allergy to Shellfish	Food allergy	1996	Present
Allergy to Iodine	Iodine allergy	1996	Present
Mitral Valve Prolapse	Mitral valve prolapse	2007	Present
Hypertension	Hypertension	2012	Present

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1027 10271105; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 28AUG2020; Date of Last Dose: 28AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	28AUG2020 (1)	15:00

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	MUSC	Back pain	Lower back pain	08SEP2020 (12)		11SEP2020 (15)		4
2	MUSC	Back pain	Mid back pain	11SEP2020 (15)		14SEP2020 (18)		4
3	GENRL	Chest pain	Left-sided chest pain	08SEP2020 (12)		08SEP2020 (12)		1
4	IMMUN	Drug hypersensitivity	Allergic Reaction to investigational product	29AUG2020 (2)		11SEP2020 (15)		14
5	GASTR	Gastrooesophageal reflux disease	GERD	08SEP2020 (12)		ONGOING		
6	NERV	Hypoaesthesia	Right arm numbness	11SEP2020 (15)		11SEP2020 (15)		1
7	MUSC	Muscular weakness	Right leg weakness	10SEP2020 (14)		10SEP2020 (14)		1
8	RESP	Pharyngeal swelling	Throat Swelling	29AUG2020 (2)		08SEP2020 (12)		11

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: GERD	1	12	N
2	1	N	N	Resolved (14SEP2020)	NOT RELATED/OTHER: GERD	1	15	N
3	1	TC	N	Resolved (08SEP2020)	NOT RELATED/OTHER: Gerd	1	12	N
4	2	TC/P	N	Resolved (11SEP2020)	Study Treatment	1	2	Y
5	1	TC	N	Yes	NOT RELATED/OTHER: acid reflux	1	12	N

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1027 10271105; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 28AUG2020; Date of Last Dose: 28AUG2020

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
6	1	N	N	Resolved (11SEP2020)	NOT RELATED/OTHER: Unknown	1	15	N
7	2	TCN	N	Resolved (10SEP2020)	NOT RELATED/OTHER: Unknown	1	14	N
8	2	TC	N	Resolved (08SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28AUG2020	
Withdrawn	VACCINATION	11SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: Jnda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1027 10271105; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 28AUG2020; Date of Last Dose: 28AUG2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1027 10271105, a 46-year-old black or African American female with a pertinent medical history of allergy to shellfish and iodine (since 1996), received Dose 1 on 28 Aug 2020. The subject developed pharyngeal swelling considered to be an allergic reaction to the investigational product on 29 Aug 2020, 1 day after receiving Dose 1.</p> <p>The subject experienced throat swelling and difficulty swallowing and was treated with systemic and oral corticosteroids. Her symptoms persisted and she was seen by a gastroenterologist. An endoscopy was normal.</p> <p>The pharyngeal swelling resolved on 08 Sep 2020 (Day 12) and the allergic reaction to the investigational product resolved on 11 Sep 2020 (Day 15).</p> <p>The subject was discontinued from the study intervention on 11 Sep 2020 because of the allergic reaction to the investigational product and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the allergic reaction to the investigational product was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1087 10871354; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 08SEP2020; Date of Last Dose: 08SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1997	23	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
182.88 cm	83.5 kg	25 kg/m2	08SEP2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	08SEP2020 (1)	12:36

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1087 10871354; Country: USA

Vaccine Group (as Administered): Placebo

Date of First Dose: 08SEP2020; Date of Last Dose: 08SEP2020

Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)
1	GENRL	Fatigue	Fatigue	11SEP2020 (4)		ONGOING
2	MUSC	Myalgia	Myalgia	11SEP2020 (4)		ONGOING
3	GENRL	Vaccination site pain	Soreness in Vaccine Arm	08SEP2020 (1)		ONGOING

Adverse Events										
AE Number	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			1	N	N	Yes	Study Treatment	1	4	N
2			1	P/W	N	Yes	Study Treatment	1	4	Y
3			1	N	N	Yes	Study Treatment	1	1	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1087 10871354; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 08SEP2020; Date of Last Dose: 08SEP2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08SEP2020	
Withdrawn	VACCINATION	17SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	17SEP2020	ADVERSE EVENT

Narrative Comment
<p>Subject C4591001 1087 10871354, a 23-year-old white male with no reported medical history, received Dose 1 on 08 Sep 2020. The subject experienced myalgia on 11 Sep 2020, 3 days after receiving Dose 1.</p> <p>The subject experienced vaccination site pain on 08 Sep 2020 (Day 1) and developed fatigue and myalgia on 11 Sep 2020 (Day 4).</p> <p>The subject was withdrawn from the study on 17 Sep 2020 because of the myalgia. The fatigue, myalgia, and vaccination site pain were all ongoing at the time of withdrawal.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1090 10901507; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 16OCT2020; Date of Last Dose: 11MAR2021

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1989	31	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
164.6 cm	80.6 kg	29.7 kg/m2	16OCT2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Anxiety	Anxiety	2007	Present
Recurrent Constipation	Constipation	2007	Present
Depression	Depression	2007	Present
Irritable Bowel Syndrome	Irritable bowel syndrome	2007	Present

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1090 10901507; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 16OCT2020; Date of Last Dose: 11MAR2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	16OCT2020 (1)	11:18
3	BNT162b2	11MAR2021 (147)	13:07

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Urticaria	Hives, upper chest	19OCT2020 (4)		22OCT2020 (7)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	4	2	TC/P	N	Resolved (22OCT2020)	Study Treatment	1	4	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1090 10901507; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 16OCT2020; Date of Last Dose: 11MAR2021

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Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	16OCT2020	
Withdrawn	VACCINATION	04NOV2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	11MAR2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1090 10901507, a 31-year-old black or African American female with a pertinent medical history of anxiety (since 2007), received Dose 1 on 16 Oct 2020. The subject experienced urticaria (hives, upper chest) on 19 Oct 2020, 3 days after receiving Dose 1.</p> <p>On 22 Oct 2020 (Day 7), the urticaria resolved.</p> <p>The subject was discontinued from the study intervention on 04 Nov 2020 because of the urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first dose of BNT162b2 on 11 Mar 2021 (Day 147) and remains in the study.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1125 11251243; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 08DEC2020; Date of Last Dose: 08DEC2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 2003	17	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
165.1 cm	60 kg	22 kg/m2	08DEC2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Seasonal allergies	Seasonal allergy	2004	Present
Tonsillectomy	Tonsillectomy	2005	Past
Tonsillitis	Tonsillitis	2005	Past

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1125 11251243; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 08DEC2020; Date of Last Dose: 08DEC2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	08DEC2020 (1)	18:03

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NERV	Headache	Grade 3 Headache	09DEC2020 (2)		09DEC2020 (2)	
2	GENRL	Injection site pain	Grade 3 Pain at Injection site	09DEC2020 (2)		09DEC2020 (2)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	3	TC/P	N	Resolved (09DEC2020)	Study Treatment	1	2	Y
2	1	3	P	N	Resolved (09DEC2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1125 11251243; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 08DEC2020; Date of Last Dose: 08DEC2020

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	08DEC2020	
Withdrawn	VACCINATION	09DEC2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1125 11251243, a 17-year-old white male with a pertinent medical history of seasonal allergy (since 2004), received Dose 1 on 08 Dec 2020. The subject experienced severe headache and injection site pain on 09 Dec 2020, 1 day after receiving Dose 1.</p> <p>On the same day (Day 2), the headache and injection site pain resolved.</p> <p>The subject was discontinued from the study intervention on 09 Dec 2020 because of the headache and injection site pain and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the headache and injection site pain were related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1134 11341153; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 24AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1976	44	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
156.21 cm	57.73 kg	23.6 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
tonsillitis	Tonsillitis	1990	Past
tonsillectomy	Tonsillectomy	1993	Past
anxiety	Anxiety	2000	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2000	Present
cholecystectomy	Cholecystectomy	2008	Past
allergic rhinitis	Rhinitis allergic	2010	Present
breast cancer	Breast cancer	2016	Past
bilateral mastectomy	Mastectomy	2017	Past
post menopausal	Postmenopause	2017	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1134 11341153; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 24AUG2020

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	24AUG2020 (1)	16:10

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GASTR	Abdominal discomfort	upset stomach	25AUG2020 (2)		21SEP2020 (29)	
2	GASTR	Diarrhoea	diarrhea	25AUG2020 (2)		25AUG2020 (2)	
3	GASTR	Diarrhoea	loose stools	25AUG2020 (2)		21SEP2020 (29)	
4	EYE	Eye pain	right eye pain	25AUG2020 (2)		21SEP2020 (29)	
5	GENRL	Fatigue	fatigue	25AUG2020 (2)		21SEP2020 (29)	
6	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
7	NERV	Headache	headache	25AUG2020 (2)		25AUG2020 (2)	
8	MUSC	Muscular weakness	muscle weakness	25AUG2020 (2)		21SEP2020 (29)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	28	2	TC	N	Resolved (21SEP2020)	Study Treatment	1	2	N
2	1	1	N	N	Resolved (25AUG2020)	Study Treatment	1	2	N
3	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1134 11341153; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 24AUG2020

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
4	28	2	P	N	Resolved (21SEP2020)	Study Treatment	1	2	Y
5	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N
6	1	1	N	N	Resolved (25AUG2020)	Study Treatment	1	2	N
7	1	2	TC	N	Resolved (25AUG2020)	Study Treatment	1	2	N
8	28	2	N	N	Resolved (21SEP2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	25AUG2020	ADVERSE EVENT

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: Jnda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1134 11341153; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 24AUG2020; Date of Last Dose: 24AUG2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1134 11341153, a 44-year-old white female with a pertinent medical history of anxiety (since 2000), attention deficit hyperactivity disorder (since 2000), allergic rhinitis (since 2010), and breast cancer (in 2016), received Dose 1 on 24 Aug 2020. On 25 Aug 2020, the subject reported right eye pain, 1 day after receiving Dose 1.</p> <p>On 25 Aug 2020 (Day 2), the subject also experienced fatigue, headache (2 episodes), abdominal discomfort, diarrhea, loose stools, and muscular weakness. The diarrhea and headache resolved on the same day (Day 2). On 21 Sep 2020 (Day 29), the abdominal discomfort, loose stools, right eye pain, fatigue, and muscular weakness resolved. The subject was discontinued from the study intervention on 25 Aug 2020 because of the right eye pain and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the right eye pain was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1134 11341174; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 26AUG2020; Date of Last Dose: 26AUG2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1984	36	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
158.75 cm	79.18 kg	31.4 kg/m2	26AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
hospitalization for childbirth	Delivery	2015	Past
hospitalization for childbirth	Delivery	2017	Past
headache	Headache	2018	Present
stress induced muscle pain in back	Back pain	JUN2020	Present

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1134 11341174; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 26AUG2020; Date of Last Dose: 26AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	26AUG2020 (1)	11:05

Adverse Events								
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)
1	GENRL	Chest discomfort	CHEST TIGHTNESS	30AUG2020 (5)		06SEP2020 (12)		8
2	NERV	Headache	WORSENING HEADACHE	27AUG2020 (2)		03SEP2020 (9)		8
3	METAB	Hypokalaemia	HYPOKALEMIA	30AUG2020 (5)		01SEP2020 (7)		3
4	GENRL	Injection site pain	PAIN AT INJECTION SITE	26AUG2020 (1)		30AUG2020 (5)		5
5	MUSC	Pain in extremity	ARM PAIN (LEFT)	28AUG2020 (3)		02SEP2020 (8)		6

Adverse Events								
AE Number	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	2	TC	N	Resolved (06SEP2020)	Study Treatment	1	5	N
2	2	TC/P	N	Resolved (03SEP2020)	Study Treatment	1	2	Y
3	1	TC	N	Resolved (01SEP2020)	NOT RELATED/OTHER: IDIOPATHIC	1	5	N
4	3	N	N	Resolved (30AUG2020)	Study Treatment	1	1	N
5	3	TC	N	Resolved (02SEP2020)	Study Treatment	1	3	N

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1134 11341174; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 26AUG2020; Date of Last Dose: 26AUG2020

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	26AUG2020	
Withdrawn	VACCINATION	30AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1134 11341174; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 26AUG2020; Date of Last Dose: 26AUG2020

Narrative Comment

Subject C4591001 1134 11341174, a 36-year-old white female with a pertinent medical history of headache (since 2018) and back pain (since Jun 2020), received Dose 1 on 26 Aug 2020.

On 26 Aug 2020, after Dose 1 administration, the subject experienced severe injection site pain. On 27 Aug 2020, 1 day after receiving Dose 1, she experienced worsening of headache. On 28 Aug 2020 (Day 3), she experienced pain in extremity (left arm pain). On 30 Aug 2020 (Day 5), the injection site pain resolved and the subject developed chest discomfort. The pain in extremity, worsening headache, and chest discomfort resolved on 02 Sep 2020 (Day 8), 03 Sep 2020 (Day 9), and 06 Sep 2020 (Day 12), respectively.

On 30 Aug 2020, the subject was discontinued from the study intervention because of the worsening headache and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

In the opinion of the investigator, there was a reasonable possibility that the worsening headache was related to the study intervention.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1163 11631059; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 07AUG2020; Date of Last Dose: 08FEB2021

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1989	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
162.56 cm	69.55 kg	26.3 kg/m2	07AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	07AUG2020 (1)	12:19
3	BNT162b2	19JAN2021 (166)	10:34
4	BNT162b2	08FEB2021 (186)	10:08

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File: Jnda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1163 11631059; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 07AUG2020; Date of Last Dose: 08FEB2021

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Dermatitis allergic	Allergic Reaction upper body rash	08AUG2020 (2)	08:00	25AUG2020 (19)	
2	IMMUN	Drug hypersensitivity	Allergic Reaction to study investigational product	08AUG2020 (2)	08:00	25AUG2020 (19)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC	N	Resolved (25AUG2020)	Study Treatment	1	2	N
2	18	2	TC/P	N	Resolved (25AUG2020)	Study Treatment	1	2	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
File: /nda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1163 11631059; Country: USA
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: 07AUG2020; Date of Last Dose: 08FEB2021

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	07AUG2020	
Withdrawn	VACCINATION	08AUG2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	19JAN2021	
Completed	OPEN LABEL TREATMENT	08MAR2021	
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1163 11631059, a 30-year-old white female with no reported medical history, received Dose 1 on 07 Aug 2020. The subject developed drug hypersensitivity (allergic reaction to study intervention) on 08 Aug 2020, 1 day after receiving Dose 1.</p> <p>On 08 Aug 2020 (Day 2), the subject developed allergic dermatitis (allergic reaction upper body rash). The drug hypersensitivity and allergic dermatitis resolved on 25 Aug 2020 (Day 19).</p> <p>The subject was discontinued from the study intervention on 08 Aug 2020 because of the drug hypersensitivity.</p> <p>In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 19 Jan 2021 (Day 166) and 08 Feb 2021 (Day 186), respectively, and remains in the study.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the drug hypersensitivity was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1166 11661047; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 31AUG2020; Date of Last Dose: 31AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1970	50	Black or African American	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
177.3 cm	60.7 kg	19.3 kg/m2	31AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Flat feet	Foot deformity	1980	Present
Scoliosis	Scoliosis	1980	Present
Smoker	Tobacco user	1988	Present
Left leg femoral artery repair	Arterial repair	2011	Past

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1166 11661047; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 31AUG2020; Date of Last Dose: 31AUG2020

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	31AUG2020 (1)	14:56

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	NERV	Dizziness	Dizziness	31AUG2020 (1)	15:30	31AUG2020 (1)	17:30

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	1	P	N	Resolved (31AUG2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001
Reason(s) for Narrative: Safety-Related Subject Withdrawal
Unique Subject ID: C4591001 1166 11661047; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 31AUG2020; Date of Last Dose: 31AUG2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	31AUG2020	
Withdrawn	VACCINATION	31AUG2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1166 11661047, a 50-year-old black or African American male with a pertinent medical history of left leg femoral artery repair (in 2011), received Dose 1 on 31 Aug 2020. On 31 Aug 2020, approximately half an hour after receiving Dose 1, the subject reported mild dizziness at 1530 hours, which resolved on the same day at 1730 hours.</p> <p>The subject was discontinued from the study intervention on 31 Aug 2020 because of the dizziness and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the dizziness was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal, Lymphadenopathy

Unique Subject ID: C4591001 1178 11781107; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 04SEP2020; Date of Last Dose: 04SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1972	48	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
175.26 cm	113.64 kg	36.9 kg/m2	04SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
seasonal allergies	Seasonal allergy	1977	Present
sinus headache	Sinus headache	1977	Present
pitocin allergy	Drug hypersensitivity	1998	Present
benign paroxysmal vertigo	Vertigo positional	1998	Present
menorrhagia	Menorrhagia	2003	Past
uterine fibroids	Uterine leiomyoma	2003	Past
hysterectomy	Hysterectomy	2005	Past
osteoarthritis, bilateral knees and feet	Osteoarthritis	2015	Present
eczema	Eczema	2017	Present

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal, Lymphadenopathy

Unique Subject ID: C4591001 1178 11781107; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 04SEP2020; Date of Last Dose: 04SEP2020

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Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	04SEP2020 (1)	13:38

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Chills	chills	05SEP2020 (2)	18:00	05SEP2020 (2)	20:00
2	GENRL	Injection site erythema	injection site redness	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
3	GENRL	Injection site pain	injection site muscle soreness	04SEP2020 (1)	19:00	06SEP2020 (3)	
4	GENRL	Injection site warmth	injection site warmth	04SEP2020 (1)	19:00	05SEP2020 (2)	19:00
5	BLOOD	Lymphadenopathy	right axilla lymphadenopathy	16SEP2020 (13)		20NOV2020 (78)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	1	1	TC	N	Resolved (05SEP2020)	Study Treatment	1	2	N
2	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
3	3	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
4	2	1	N	N	Resolved (05SEP2020)	Study Treatment	1	1	N
5	66	2	TC/P	Y	Resolved (20NOV2020)	Study Treatment	1	13	Y

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal, Lymphadenopathy

Unique Subject ID: C4591001 1178 11781107; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 04SEP2020; Date of Last Dose: 04SEP2020

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	04SEP2020	
Withdrawn	VACCINATION	25SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Related Serious Adverse Event, Safety-Related Subject Withdrawal, Lymphadenopathy

Unique Subject ID: C4591001 1178 11781107; Country: USA

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 04SEP2020; Date of Last Dose: 04SEP2020

Narrative Comment

Subject C4591001 1178 11781107, a 48-year-old white female with a pertinent medical history of drug hypersensitivity to Pitocin, received Dose 1 on 04 Sep 2020 in her left deltoid. The subject was diagnosed with lymphadenopathy on 16 Sep 2020, 12 days after receiving Dose 1.

Concomitant medications included ibuprofen (since 2000) for headache and osteoarthritis, cetirizine hydrochloride (since 2015) for seasonal allergies, and crisaborole (since 2017) for eczema.

On 04 Sep 2020 (Day 1), approximately 6 hours after Dose 1 administration, the subject reported mild injection site erythema and warmth and moderate injection site pain. On 05 Sep 2020 (Day 2), she reported mild chills. That same day (Day 2), the injection site erythema, warmth, and chills were considered resolved, and on 06 Sep 2020 (Day 3), the injection site pain resolved. On 16 Sep 2020 (Day 13), the subject reported discomfort in her right arm, shoulder, and chest region, which she described as feeling like a pulled muscle, even at rest. Additionally, the subject reported that her physician referred her to the regional hospital emergency room (ER) for further evaluation. On 20 Sep 2020 (Day 17), the subject visited the ER, at which time her right axilla was examined, and a subsequent ultrasound examination of the right axilla on the same day revealed at least 4 enlarged lymph nodes; the largest was $2.5 \times 1.1 \times 2.4$ cm. The laboratory results on the same day showed a white blood cell count of 7.0 k/ μ L (normal range [NR]: 4.0-10.0 k/ μ L) with 35.2% lymphocytes (NR: 20%-40%), and an absolute lymphocyte count of 2.4 k/ μ L (NR: 1.0-4.0 k/ μ L). The subject denied any injuries, cuts, or puncture wounds to the right arm or having had a similar problem previously. It was reported that no other areas other than the right axilla were assessed for lymphadenopathy. The subject received ketorolac 10 mg intravenously once (on 20 Sep 2020) while in the ER for lymphadenopathy. The lymphadenopathy was considered medically significant by the investigator. A biopsy was completed on 05 Oct 2020 (Day 32) without issue. On 12 Oct 2020 (Day 39), the subject communicated via telephone the results of her workup, stating that her blood tests returned to normal and the biopsy showed no markers for lymphoma or other cancer. Per subject report, the oncologist considered the vaccine as the most likely etiology for her lymphadenopathy. The lymphadenopathy was considered resolved on 20 Nov 2020 (Day 78). A follow-up oncological visit was planned in 3 months with a possible repeat of the axillary ultrasonography. The subject was scheduled to have a follow-up visit and ultrasound examination on 29 Dec 2020 (Day 117).

The subject was discontinued from the study intervention on 25 Sep 2020 because of the lymphadenopathy and remains in the study to be evaluated for safety, immunogenicity, and efficacy.

In the opinion of the investigator, there was a reasonable possibility that the lymphadenopathy was related to the study intervention, but not related to concomitant medications or clinical trial procedures. Pfizer did not assess the lymphadenopathy as related to the study intervention and considered that there was not enough evidence to establish a causal relationship with the study intervention apart from a chronological association at the time of this report. It was also noted that the subject received the study intervention in the left deltoid and the lymphadenopathy was in the right axillary area.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1224 12241065; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 22FEB2021

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1990	30	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
170.43 cm	65.45 kg	22.5 kg/m2	24AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Acne	Acne	2017	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	24AUG2020 (1)	10:47

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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1224 12241065; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 22FEB2021

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
3	BNT162b2	01FEB2021 (162)	14:24
4	BNT162b2	22FEB2021 (183)	10:50

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INV	Blood pressure increased	Increased Blood Pressure	24AUG2020 (1)		10SEP2020 (18)	
2	GASTR	Diarrhoea	Diarrhea	24AUG2020 (1)		06SEP2020 (14)	
3	GENRL	Fatigue	Fatigue	24AUG2020 (1)		02SEP2020 (10)	
4	INV	Heart rate irregular	Irregular Heart Rate	24AUG2020 (1)		10SEP2020 (18)	
5	GENRL	Pyrexia	Feverish Chills	24AUG2020 (1)		02SEP2020 (10)	

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	N	N	Resolved (10SEP2020)	Study Treatment	1	1	N
2	14	2	N	N	Resolved (06SEP2020)	Study Treatment	1	1	N
3	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N
4	18	2	P	N	Resolved (10SEP2020)	Study Treatment	1	1	Y
5	10	2	N	N	Resolved (02SEP2020)	Study Treatment	1	1	N

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1224 12241065; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 22FEB2021

Prohibited Concomitant Medications

No Prohibited Concomitant Medications

Nonstudy Vaccines

No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	24AUG2020	
Withdrawn	VACCINATION	05SEP2020	ADVERSE EVENT
Completed	REPEAT SCREENING 1	01FEB2021	
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1224 12241065; Country: USA

Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)

Date of First Dose: 24AUG2020; Date of Last Dose: 22FEB2021

Narrative Comment

Subject C4591001 1224 12241065, a 30-year-old white female with no pertinent medical history, received Dose 1 on 24 Aug 2020. The subject was diagnosed with an irregular heart rate on 24 Aug 2020, the day of Dose 1 administration.

On 24 Aug 2020 (Day 1), the subject also experienced increased blood pressure, diarrhea, fatigue, and pyrexia. The fatigue and pyrexia resolved on 02 Sep 2020 (Day 10), the diarrhea resolved on 06 Sep 2020 (Day 14), and the increased blood pressure and irregular heart rate resolved on 10 Sep 2020 (Day 18).

The subject was withdrawn from the study intervention on 05 Sep 2020 because of the irregular heart rate.

In accordance with the protocol allowance, the subject agreed to be unblinded to determine whether she was eligible for receipt of BNT162b2. It was confirmed that she had originally received placebo; the subject therefore received the first and second doses of BNT162b2 on 01 Feb 2021 (Day 162) and 22 Feb 2021 (Day 183), respectively, and remains in the study.

In the opinion of the investigator, there was a reasonable possibility that the irregular heart rate was related to the study intervention.

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1226 12261072; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 11AUG2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1978	42	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
169.5 cm	83.7 kg	29.1 kg/m2	11AUG2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Hypothyroidism	Hypothyroidism	2010	Present
Anxiety	Anxiety	2016	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	11AUG2020 (1)	09:52

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
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Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1226 12261072; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 11AUG2020

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Adverse Events						
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)
1	MUSC	Myalgia	Muscle pain (shoulders and neck, on the right body side)	18AUG2020 (8)		ONGOING

Adverse Events										
AE Number	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1			2	TC/P/W	N	Yes	Study Treatment	1	8	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1226 12261072; Country: Brazil

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 11AUG2020; Date of Last Dose: 11AUG2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	11AUG2020	
Withdrawn	VACCINATION	01SEP2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	14OCT2020	ADVERSE EVENT

Narrative Comment
<p>Subject C4591001 1226 12261072, a 42-year-old white female with a pertinent medical history of hypothyroidism (since 2010) and anxiety (since 2016), received Dose 1 on 11 Aug 2020. The subject experienced myalgia (shoulders and neck, on the right body side) on 18 Aug 2020, 7 days after receiving Dose 1.</p> <p>The subject was discontinued from the study intervention on 01 Sep 2020 and was withdrawn from the study on 14 Oct 2020 because of the myalgia, which was ongoing at the time of withdrawal.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the myalgia was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1231 12315429; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 30AUG2020; Date of Last Dose: 30AUG2020

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Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1983	37	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
156 cm	54 kg	22.2 kg/m2	30AUG2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	30AUG2020 (1)	10:34

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
File: Jnda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1231 12315429; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 30AUG2020; Date of Last Dose: 30AUG2020

Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Injection site pain	pain at injection site	30AUG2020 (1)	10:34	16SEP2020 (18)	09:00

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	18	2	TC/P/W	N	Resolved (16SEP2020)	Study Treatment	1	1	Y

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1231 12315429; Country: Argentina

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 30AUG2020; Date of Last Dose: 30AUG2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30AUG2020	
Withdrawn	VACCINATION	05OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
Withdrawn	FOLLOW-UP	05OCT2020	ADVERSE EVENT

Narrative Comment
<p>Subject C4591001 1231 12315429, a 37-year-old white female with no reported medical history, received Dose 1 on 30 Aug 2020. The subject reported moderate injection site pain on 30 Aug 2020, after Dose 1 administration.</p> <p>The injection site pain resolved on 16 Sep 2020 (Day 18).</p> <p>The subject was withdrawn from the study on 05 Oct 2020 because of the injection site pain.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the injection site pain was related to the study intervention.</p>

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1246 12461025; Country: South Africa

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 28SEP2020; Date of Last Dose: 28SEP2020

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
(b) (6) 1975	45	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
172 cm	62 kg	21 kg/m2	28SEP2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Hysterectomy	Hysterectomy	1998	Past
Asthma	Asthma	2015	Past

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	28SEP2020 (1)	10:30

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output
File: Jnda2_unblinded/C4591001_BLA_Narrative_Safety/profile Date of Generation: 01APR2021 (10:49)

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1246 12461025; Country: South Africa

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 28SEP2020; Date of Last Dose: 28SEP2020

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Adverse Events							
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	SKIN	Urticaria	Intermittent urticaria generalised.	07OCT2020 (10)		02NOV2020 (36)	
2	SKIN	Urticaria	urticaria generalized	29SEP2020 (2)	00:01	02OCT2020 (5)	18:15

Adverse Events									
AE Number	Duration (Days)	Toxicity Grade	Action to Subject	SAE	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	27	2	TC/P	N	Resolved (02NOV2020)	Study Treatment	1	10	Y
2	4	3	TC	N	Resolved (02OCT2020)	Study Treatment	1	2	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Compound: PF-07302048; Protocol: C4591001

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Reason(s) for Narrative: Safety-Related Subject Withdrawal

Unique Subject ID: C4591001 1246 12461025; Country: South Africa

Vaccine Group (as Administered): BNT162b2 (30 µg)

Date of First Dose: 28SEP2020; Date of Last Dose: 28SEP2020

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	28SEP2020	
Withdrawn	VACCINATION	19OCT2020	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
<p>Subject C4591001 1246 12461025, a 45-year-old white female with a pertinent medical history of asthma (in 2015), received Dose 1 on 28 Sep 2020. The subject reported urticaria on 2 occasions after receiving Dose 1.</p> <p>The subject had an initial episode of urticaria on 29 Sep 2020 (Day 2) lasting until 02 Oct 2020 (Day 5). The second episode took place on 07 Oct 2020 (Day 10) lasting until 02 Nov 2020 (Day 36).</p> <p>The subject was discontinued from the study intervention on 19 Oct 2020 because of the additional episode of urticaria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.</p> <p>In the opinion of the investigator, there was a reasonable possibility that the urticaria was related to the study intervention.</p>