Table of Abbreviations		
Category	**Abbreviation**	**Text**
Action - Subject	N	No action
	O	Other
	P	Drug withdrawn (study intervention discontinued)
	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders

Table of Abbreviations		
Category	**Abbreviation**	**Text**
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.72 cm	67.27 kg	22.5 kg/m2	16DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	2010	Present
Separation Anxiety Disorder	Separation anxiety disorder	2010	Present
Disruptive Mood Dysregulation Disorder	Disruptive mood dysregulation disorder	2012	Present
Asthma	Asthma	2013	Present
Anxiety	Anxiety	2014	Present
Depression	Depression	2014	Present
Recurring Insomnia	Insomnia	2014	Present
Recurring Nightmares	Nightmare	2015	Present
Post Traumatic Stress Disorder	Post-traumatic stress disorder	06NOV2015	Present
Aggressive Behaviors	Aggression	2017	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	16DEC2020 (1)	12:07

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	PSYCH	Anxiety	Worsening of anxiety	23DEC2020 (8)		18JAN2021 (34)		27
2	INJ&P	Contusion	Contusion left elbow	05FEB2021 (52)		ONGOING		
3	PSYCH	Depression	Worsening of Depression	23DEC2020 (8)		18JAN2021 (34)		27

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	3	TC/TCN/P	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: Stress	1	8	Y
2	1	N	N	Yes	NOT RELATED/OTHER: Fall on ice	1	52	N
3	3	TC/TCN/P	Y	Resolved (18JAN2021)	NOT RELATED/OTHER: Stress	1	8	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	16DEC2020	
Withdrawn	VACCINATION	06JAN2021	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1006 10061272, a 13-year-old black or African American female with a pertinent medical history of attention deficit hyperactivity disorder and separation anxiety disorder (both since 2010); disruptive mood dysregulation disorder (since 2012); anxiety, depression, and recurring insomnia (all since 2014); recurring nightmares (since 2015); posttraumatic stress disorder (since 06 Nov 2015); and aggression (in 2017 with 4 days' hospitalization), received Dose 1 on 16 Dec 2020. The family medical history was pertinent for posttraumatic stress disorder, borderline personality disorder (b) (6)), and drug addiction (b) (6)). The subject experienced worsening of anxiety and worsening of depression on 23 Dec 2020, 7 days after receiving Dose 1. Concomitant medications included salbutamol and fluticasone propionate (both since 2013) and montelukast sodium (from 2013 to 30 Dec 2020) for asthma; and duloxetine hydrochloride (from 2019 to 30 Dec 2020) and citalopram hydrobromide (from Oct 2020 to 30 Dec 2020), both for depression. The subject, with an ongoing medical history of anxiety and depression, which were stable at Visit 1, experienced worsening of anxiety and depression after Visit 1 on 23 Dec 2020 (Day 8) and was hospitalized for 14 days. During hospitalization, the subject was seen by a physician and was treated with aripiprazole 1 mg and venlafaxine 150 mg per day (starting on 30 Dec 2020) and the physician recommended admission to an inpatient residential treatment/psychiatric facility. On 05 Jan 2021 (Day 21), the subject was admitted to an inpatient residential treatment/psychiatric facility for medical management and stabilization. The subject was not tested for COVID-19. During a scheduled visit, the subject and her guardian stated that the subject's mental health had stabilized, and she was treated with trazodone 50 mg every night (from 06 Jan 2021) for her history of recurring insomnia. On 18 Jan 2021 (Day 34), the worsening of anxiety and worsening of depression resolved and the subject was discharged from the hospital on the same day. The subject was discontinued from the study intervention on 06 Jan 2021 because of the worsening of anxiety and depression and remains in the study to be evaluated for safety, immunogenicity, and efficacy. In the opinion of the investigator, there was no reasonable possibility that the worsening of anxiety and worsening of depression were related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to stress. Pfizer did not assess the worsening of anxiety and worsening of depression as related to the study intervention, concomitant medications, or clinical trial procedures.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	76 kg	27 kg/m2	05JAN2021 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05JAN2021 (1)	17:10

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	GENRL	Pyrexia	Fever (104.7)	06JAN2021 (2)	19:30	08JAN2021 (4)	

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	4	TC/P	N	Resolved (08JAN2021)	Study Treatment	1	2	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	05JAN2021	
Withdrawn	VACCINATION	08JAN2021	ADVERSE EVENT
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471327, a 14-year-old white male with no reported medical history, received Dose 1 on 05 Jan 2021. The subject experienced pyrexia (fever 104.7°F) on 06 Jan 2021, 1 day after receiving Dose 1. The pyrexia resolved on 08 Jan 2021 (Day 4). The subject was discontinued from the study intervention on 08 Jan 2021 because of the pyrexia 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 pyrexia was related to the study intervention.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175 cm	64.8 kg	21.2 kg/m2	17DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ADHD	Attention deficit hyperactivity disorder	2012	Present
Migraine	Migraine	2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	17DEC2020 (1)	15:49
2	Placebo	07JAN2021 (22)	15:49

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time
1	INFEC	Appendicitis	Appendicitis	11MAR2021 (85)		ONGOING	

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	TC	Y	Yes	NOT RELATED/OTHER: Infection	2	64	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	17DEC2020	
Completed	VACCINATION	04FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment

Subject C4591001 1007 10071581, a 15-year-old white male with no pertinent medical history, received Dose 1 on 17 Dec 2020 and Dose 2 on 07 Jan 2021 (Day 22). The subject was diagnosed with appendicitis on 11 Mar 2021, 63 days after receiving Dose 2.

On 11 Mar 2021 (Day 85), the subject presented to the emergency room with worsening of abdominal pain that localized to the right lower quadrant for a day. The subject was subsequently hospitalized for nonoperative pain management. An abdominal ultrasound scan was consistent with acute appendicitis, and the appendix was visualized. The subject remained afebrile while hospitalized. Relevant laboratory tests performed on the same day (Day 85) showed an elevated red blood cell count of 5.43 (normal range [NR]: 4.5-5.3) and lymphocytes of 47.8 (NR: 34.0-42.0); decreased segmented neutrophils of 39.9 (NR: 40.0-62.0); and normal white blood cell (WBC) count of 6.94 (NR: 4.5-13.5), hemoglobin of 15.3 (NR: 13.0-16.0), hematocrit of 44.9 (NR: 37.0-49.0), and platelet count of 357 (NR: 135-466) (units not reported for all the laboratory values). A SARS-CoV-2 test performed on 11 Mar 2021 (Day 85) was negative. During hospitalization, the subject received a single dose of intravenous (IV) metronidazole 1000 mg and IV ceftriaxone 2000 mg, both on 11 Mar 2021 (Day 85). On 12 Mar 2020 (Day 86), the subject was discharged from the hospital on oral (PO) amoxicillin-clavulanate 875/125-mg tablet twice a day for 14 days, PO ibuprofen 600 mg every 6 hours as needed (PRN) for moderate pain, and PO acetaminophen 325 mg every 4 to 6 hours PRN for pain. The appendicitis was ongoing at the time of the last available report.

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.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
172.5 cm	67.65 kg	22.7 kg/m2	12DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Constipation	Constipation	02JUL2014	Present
Perforation of right tympanic membrane	Tympanic membrane perforation	02JUL2014	Present
Psoriasis	Psoriasis	2016	Present
Other iron deficiency anemia	Iron deficiency anaemia	27MAY2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12DEC2020 (1)	10:44
2	Placebo	04JAN2021 (24)	16:37

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	Appendicitis	Acute appendicitis	22JAN2021 (42)	16:00	23JAN2021 (43)	00:01	2	4
2	INFEC	Focal peritonitis	localized peritonitis, without perforation or gangrene	22JAN2021 (42)	16:00	23JAN2021 (43)	00:01	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/TCN	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: Acute appendicitis	2	19	Y
2	TC/TCN	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: Acute appendicitis	2	19	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	12DEC2020	
Completed	VACCINATION	06FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1147 11471281, a 13-year-old white male with a pertinent medical history of constipation (since 02 Jul 2014), psoriasis (since 2016), and iron deficiency anemia (since 27 May 2020), received Dose 1 on 12 Dec 2020 and Dose 2 on 04 Jan 2021 (Day 24). The subject was diagnosed with appendicitis and focal peritonitis on 22 Jan 2021, 18 days after receiving Dose 2. Concomitant medications included polyethylene glycol (since 2013) for constipation, ferrous sulfate (since 27 May 2020) for iron deficiency anemia, and mupirocin (since 22 Dec 2020) for psoriasis. On 22 Jan 2021 (Day 42), the subject presented to the emergency room (ER) with localized acute abdominal pain in the right lower quadrant within 5 hours after the onset. It was reported that the abdominal pain was associated with anorexia. The subject was tachycardic on arrival to the ER, and the right lower quadrant was focally tender. The laboratory tests showed an elevated white blood cell count of 18.63 × 103/mm3 (normal range [NR]: 3.90-12.70 × 103/mm3), and an ultrasound scan of the abdomen was consistent with acute appendicitis with lower right quadrant pain; no findings were suggestive of appendiceal perforation. A serious adverse event of focal peritonitis (localized peritonitis without perforation or gangrene) was also reported with an onset date of 22 Jan 2021 (Day 42). Other relevant tests included an elevated absolute neutrophil count of 16 × 103/mm3 (NR: 1.8-7.7 × 103/mm3) and granulocytes of 85.8% (NR: 38%-73%); decreased lymphocytes of 7.4% (NR: 18%-48%); and immature granulocyte count of 0.07 × 103/mm3 (NR: 0.0-0.5 × 103/mm3) and monocyte count of 0.9 × 103/mm3 (NR: 0.3-1.0 × 103/mm3). The subject received unspecified intravenous (IV) fluids and immediately had a laparoscopic appendectomy procedure, which was reported to be well tolerated. On 23 Jan 2021 (Day 43), the appendicitis and focal peritonitis resolved, and the subject was discharged from the hospital. The appendicitis and focal peritonitis were considered as life-threatening events by the investigator. In the opinion of the investigator, there was no reasonable possibility that the appendicitis and focal peritonitis were related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
151 cm	39 kg	17.1 kg/m2	02DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention deficit/hyperactivity disorder	Attention deficit hyperactivity disorder	2017	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	02DEC2020 (1)	17:22
2	BNT162b2	22DEC2020 (21)	09:50

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	swollen lymph node left axilla	25DEC2020 (24)		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	2	4	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	02DEC2020	
Completed	VACCINATION	20JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155 cm	45.9 kg	19.1 kg/m2	29DEC2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	29DEC2020 (1)	16:12
2	BNT162b2	19JAN2021 (22)	16:34

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	left axillary lymph node swelling	20JAN2021 (23)		23JAN2021 (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	4	1	N	N	Resolved (23JAN2021)	Study Treatment	2	2	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	29DEC2020	
Completed	VACCINATION	23FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	44.6 kg	17.4 kg/m2	05JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Penicillin allergy	Drug hypersensitivity	01JAN2010	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	05JAN2021 (1)	10:55
2	BNT162b2	26JAN2021 (22)	10:48

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	BLOOD	Lymphadenopathy	Left deep cervical chain lymph node swelling	12JAN2021 (8)	12:30	09FEB2021 (36)		29	1	N	N
2	BLOOD	Lymphadenopathy	left Cervical lymphadenopathy	23FEB2021 (50)	07:30	ONGOING			1	N	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (09FEB2021)	Study Treatment	1	8	Y
2	Yes	NOT RELATED/OTHER: Local adenopathy. Do not think related to study agent	2	29	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	05JAN2021	
Completed	VACCINATION	23FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	57.82 kg	20.5 kg/m2	20OCT2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	20OCT2020 (1)	18:16
2	BNT162b2	09NOV2020 (21)	15:56

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	left swollen axillary lymph node	10NOV2020 (22)		10NOV2020 (22)	

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	N	N	Resolved (10NOV2020)	Study Treatment	2	2	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	20OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
175.26 cm	61.64 kg	20 kg/m2	14DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Ketamine allergy	Drug hypersensitivity	2007	Present
Allergic Rhinitis	Rhinitis allergic	2007	Present
eczema, bilateral hands	Hand dermatitis	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14DEC2020 (1)	18:25
2	BNT162b2	04JAN2021 (22)	17:11

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	BLOOD	Lymphadenopathy	swollen cervical lymph nodes bilateral	31JAN2021 (49)		02FEB2021 (51)		3

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 (02FEB2021)	NOT RELATED/OTHER: unknown	2	28	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	14DEC2020	
Completed	VACCINATION	05FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
152.4 cm	51.36 kg	22.1 kg/m2	22OCT2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
seasonal allergies	Seasonal allergy	FEB2010	Present
attention deficit disorder	Attention deficit hyperactivity disorder	SEP2014	Present
hypotension	Hypotension	MAY2017	Present
acne	Acne	JUN2017	Present
anxiety	Anxiety	AUG2017	Present
anger disorder	Anger	NOV2018	Past
oppositional defiance disorder	Oppositional defiant disorder	NOV2018	Past
moderate depression	Depression	MAY2019	Present
chronic vocal tic disorder	Chronic tic disorder	01MAY2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	22OCT2020 (1)	16:44
2	Placebo	11NOV2020 (21)	15:37

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	INFEC	Infectious mononucleosis	infectious mononuclesosis	25NOV2020 (35)		06JAN2021 (77)		43
2	BLOOD	Lymphadenopathy	enlarged lymph nodes, right anterior cervical nodes	25NOV2020 (35)		06JAN2021 (77)		43

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 (06JAN2021)	NOT RELATED/OTHER: mono infection	2	15	N
2	1	N	N	Resolved (06JAN2021)	NOT RELATED/OTHER: mono	2	15	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	22OCT2020	
Completed	VACCINATION	10DEC2020	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
169 cm	55 kg	19.3 kg/m2	04DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Laparoscopic Appendectomy	Appendicectomy	26OCT2016	Past
Appendicitis	Appendicitis	26OCT2016	Past

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	04DEC2020 (1)	16:51
2	BNT162b2	23DEC2020 (20)	15:39

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	Fall	Mechanical Fall	20DEC2020 (17)		20DEC2020 (17)		1	2
2	BLOOD	Lymphadenopathy	LEFT AXILLA LYMPH NODE SWELLING	10DEC2020 (7)		13DEC2020 (10)		4	1
3	INJ&P	Radius fracture	RIGHT DISTAL RADIUS TORUS FRACTURE	20DEC2020 (17)		20JAN2021 (48)		32	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	N	N	Resolved (20DEC2020)	NOT RELATED/OTHER: Snow boarding	1	17	N
2	N	N	Resolved (13DEC2020)	Study Treatment	1	7	Y
3	TC	N	Resolved (20JAN2021)	NOT RELATED/OTHER: MECHANICAL FALL	1	17	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	04DEC2020	
Completed	VACCINATION	20JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	Black or African American	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.3 cm	47.5 kg	19.4 kg/m2	29DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2016	Present
eczema	Eczema	2019	Present
acne	Acne	APR2020	Present
depressive symptoms	Depressive symptom	OCT2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	29DEC2020 (1)	11:35
2	Placebo	18JAN2021 (21)	13:20

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	BLOOD	Lymphadenopathy	enlarge lymph nods-neck(bilateral)	27JAN2021 (30)		03FEB2021 (37)		8	1
2	RESP	Rhinorrhoea	rhinorrhea	17JAN2021 (20)		03FEB2021 (37)		18	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 (03FEB2021)	Study Treatment	2	10	Y
2	N	N	Resolved (03FEB2021)	NOT RELATED/OTHER: unknown viral exposure	1	20	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	29DEC2020	
Completed	VACCINATION	15FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	Not Reported	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	65.82 kg	22.7 kg/m2	31DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
mild asthma	Asthma	2007	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	31DEC2020 (1)	10:42
2	BNT162b2	22JAN2021 (23)	09:57

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	BLOOD	Lymphadenopathy	left supraclavicular lymph node swelling	07JAN2021 (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			1	N	N	Yes	Study Treatment	1	8	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	31DEC2020	
Completed	VACCINATION	22FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
170.18 cm	52.18 kg	18 kg/m2	15DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
myopia	Myopia	2015	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	15DEC2020 (1)	17:06
2	BNT162b2	05JAN2021 (22)	15:56

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	BLOOD	Lymphadenopathy	Swollen Lymph Node (Left Clavicle)	26DEC2020 (12)		ONGOING			1	N	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
1	Yes	NOT RELATED/OTHER: Mild swollen lymph node from probable microbial infection, per investigator. NCS	1	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	15DEC2020	
Completed	VACCINATION	02FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.64 cm	50.64 kg	18 kg/m2	21DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
allergy to bee stings	Allergy to arthropod sting	2016	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	21DEC2020 (1)	11:21
2	BNT162b2	11JAN2021 (22)	11:58

Adverse Events							
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**	**Stop Time**
1	BLOOD	Lymphadenopathy	swollen lymph node left axilla	26DEC2020 (6)		04JAN2021 (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	10	2	N	N	Resolved (04JAN2021)	Study Treatment	1	6	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	21DEC2020	
Completed	VACCINATION	08FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
155.5 cm	57.1 kg	23.6 kg/m2	30DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention deficit disorder	Attention deficit hyperactivity disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	30DEC2020 (1)	10:26
2	BNT162b2	20JAN2021 (22)	16:30

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	GASTR	Abdominal pain	Abdominal pain	21JAN2021 (23)		09FEB2021 (42)		20	2	TC	N
2	GASTR	Abdominal pain	Functional Abdominal Pain	28FEB2021 (61)		ONGOING			3	TC	Y
3	GASTR	Constipation	Constipation	28FEB2021 (61)		ONGOING			3	TC	Y
4	SKIN	Dermatitis contact	contact dermatitis bilateral arms	12FEB2021 (45)		ONGOING			1	TC	N
5	GASTR	Gastritis	Gastritis	30JAN2021 (32)		ONGOING			2	TC	N
6	NERV	Neuralgia	generalized Functional neurologic pain	21JAN2021 (23)		ONGOING			2	TC	Y
7	INFEC	Vulval abscess	Vulvar boil	24JAN2021 (26)		26JAN2021 (28)		3	1	TC	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (09FEB2021)	Study Treatment	2	2	N
2	Yes	NOT RELATED/OTHER: no organic cause; no known precipitating factors	2	40	Y
3	Yes	NOT RELATED/OTHER: no organic cause identified	2	40	Y
4	Yes	NOT RELATED/OTHER: suspected reaction to tape	2	24	N
5	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	11	N

Adverse Events					
AE Number	**AE Still Present?**	**AE Related To:**	**Prior Vaccination Number**	**Relative Day From Prior Vaccination**	**Narrative Event**
6	Yes	NOT RELATED/OTHER: unspecified	2	2	Y
7	Resolved (26JAN2021)	NOT RELATED/OTHER: Presumed staph infection	2	5	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	30DEC2020	
Completed	VACCINATION	18FEB2021	
	REPEAT SCREENING 1		

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

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	Asian	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
177.7 cm	65.5 kg	20.7 kg/m2	11JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
asthma	Asthma	2006	Past
glasses user	Corrective lens user	2012	Present
seasonal allergic rhinitis	Seasonal allergy	2016	Present
anxiety	Anxiety	2018	Present
attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2018	Present
Depression	Depression	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	11JAN2021 (1)	12:50
2	BNT162b2	01FEB2021 (22)	08:31

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	PSYCH	Depression	Depression Exacerbation	26JAN2021 (16)		30JAN2021 (20)		5

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	3	TC/TCN	Y	Resolved (30JAN2021)	NOT RELATED/OTHER: Stress	1	16	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	11JAN2021	
Completed	VACCINATION	04MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.5 cm	50.7 kg	19.2 kg/m2	28DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Seasonal allergies	Seasonal allergy	2008	Present
Attention deficit hyperactive disorder	Attention deficit hyperactivity disorder	2013	Present
Migraines	Migraine	2015	Present
Anxiety	Anxiety	OCT2018	Present
Depression	Depression	OCT2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	28DEC2020 (1)	16:52
2	BNT162b2	18JAN2021 (22)	11:50

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)
1	PSYCH	Depression	Worsening of Depression	19JAN2021 (23)		23JAN2021 (27)		5

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	Y	Resolved (23JAN2021)	NOT RELATED/OTHER: unknown	2	2	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	28DEC2020	
Completed	VACCINATION	16FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
167.6 cm	60.6 kg	21.6 kg/m2	18DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Attention Deficit Hyperactivity Disorder	Attention deficit hyperactivity disorder	JAN2015	Present
Right knee pain	Arthralgia	19JUN2020	Present
Right Forearm Pain	Pain in extremity	19JUN2020	Present
Anxiety	Anxiety	31AUG2020	Present
Depression	Depression	08DEC2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	18DEC2020 (1)	16:30
2	BNT162b2	08JAN2021 (22)	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)**
1	PSYCH	Suicidal ideation	SUICIDAL IDEATION	16FEB2021 (61)	10:17	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	3	TCN	Y	Yes	NOT RELATED/OTHER: PSYCHOSOCIAL ISSUES	2	40	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	18DEC2020	
Completed	VACCINATION	05FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
162.56 cm	49.36 kg	18.6 kg/m2	10DEC2020 (1)

Medical History
No Medical History

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	10DEC2020 (1)	12:11
2	Placebo	29DEC2020 (20)	11:37

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 face	12DEC2020 (3)		31DEC2020 (22)	
2	SKIN	Urticaria	Hives trunk	12DEC2020 (3)		15DEC2020 (6)	

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	20	1	TC	N	Resolved (31DEC2020)	Study Treatment	1	3	Y
2	4	1	TC	N	Resolved (15DEC2020)	Study Treatment	1	3	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	10DEC2020	
Completed	VACCINATION	26JAN2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2008	12	White	Non-Hispanic/non-Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
168 cm	89.4 kg	31.7 kg/m2	17DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
ADHD, predominantly inattentive type	Attention deficit hyperactivity disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	17DEC2020 (1)	16:27
2	Placebo	07JAN2021 (22)	15:58

Adverse Events						
AE Number	**MedDRA SOC**	**MedDRA Preferred Term**	**Investigator Text**	**Start Date (Study Day)**	**Start Time**	**Stop Date (Study Day)**
1	SKIN	Urticaria	hives; trunk, abdomen, back	16JAN2021 (31)		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	N	Yes	Study Treatment	2	10	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	17DEC2020	
Completed	VACCINATION	04FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
163.83 cm	74.09 kg	27.5 kg/m2	08JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Sulfa allergy	Drug hypersensitivity	2014	Present
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2016	Present
Anxiety	Anxiety	2018	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	08JAN2021 (1)	15:23
2	BNT162b2	29JAN2021 (22)	14:26

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	urticaria multiple sites	10JAN2021 (3)		22JAN2021 (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	13	1	TC	N	Resolved (22JAN2021)	Study Treatment	1	3	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	08JAN2021	
Completed	VACCINATION	26FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2005	15	White	Hispanic/Latino	M

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
182.4 cm	84.7 kg	25.5 kg/m2	12JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
penicillin allergy	Drug hypersensitivity	2007	Present
recurrent diarrhea	Diarrhoea	2010	Present
tonsillectomy	Tonsillectomy	2011	Past
eczema, bilateral arms	Eczema	2012	Past
acne	Acne	2018	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12JAN2021 (1)	12:09
2	Placebo	03FEB2021 (23)	07:51

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	urticaria, both hands	04FEB2021 (24)		06FEB2021 (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	3	1	N	N	Resolved (06FEB2021)	Study Treatment	2	2	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	12JAN2021	
Completed	VACCINATION	09MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2006	14	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
156.2 cm	43.9 kg	18 kg/m2	12JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
GERD	Gastrooesophageal reflux disease	2006	Present
Allergic Rhinitis	Rhinitis allergic	2011	Present
anxiety	Anxiety	2018	Present
Obsessive-compulsive disorder	Obsessive-compulsive disorder	2020	Present

Study Vaccination(s)

Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	Placebo	12JAN2021 (1)	10:33
2	Placebo	04FEB2021 (24)	10:04

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	PSYCH	Anxiety	Worsening of Anxiety	05MAR2021 (53)		ONGOING			2
2	SKIN	Urticaria	hives forehead	12JAN2021 (1)	11:29	12JAN2021 (1)		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	TC	N	Yes	NOT RELATED/OTHER: medication dosage adjustment	2	30	N
2	N	N	Resolved (12JAN2021)	Study Treatment	1	1	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	12JAN2021	
Completed	VACCINATION	09MAR2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	White	Non-Hispanic/non-Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
140.6 cm	33 kg	16.7 kg/m2	14DEC2020 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Premenarchal	Premenarche	(b) (6) 2007	Present
Allergy to Bee Venom	Allergy to arthropod sting	07OCT2010	Present
Urticaria, No Known Triggers	Urticaria	07OCT2010	Present
Left Proximal Radius Fracture	Radius fracture	27JUL2012	Past
Verruca Vulgaris	Skin papilloma	09NOV2017	Present
Juvenile Osteochondrosis of Right Tarsal	Osteochondrosis	25JUN2020	Present
Right Hip Flexor Strain	Muscle strain	12NOV2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	BNT162b2	14DEC2020 (1)	11:08
2	BNT162b2	05JAN2021 (23)	16:05

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	MUSC	Osteochondrosis	Juvenile Osteochondrosis of bilateral fifth metatarsals	28DEC2020 (15)		ONGOING		
2	SKIN	Urticaria	Facial Urticaria, worsening	18DEC2020 (5)		31DEC2020 (18)		14

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: Gymnastic injury	1	15	N
2	1	N	N	Resolved (31DEC2020)	NOT RELATED/OTHER: Trigger unknown	1	5	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	14DEC2020	
Completed	VACCINATION	05FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Demography				
Date of Birth	**Age at Enrollment (Years)**	**Race**	**Ethnicity**	**Sex**
(b) (6) 2007	13	American Indian or Alaska Native	Hispanic/Latino	F

Vital Signs - Baseline			
Height	**Weight**	**BMI**	**Date Collected (Study Day)**
160 cm	69.7 kg	27.2 kg/m2	07JAN2021 (1)

Medical History			
Investigator Text	**MedDRA Preferred Term**	**Start Date**	**Disease Status**
Depression	Depression	02DEC2014	Present
Asthma	Asthma	01FEB2016	Present
Anxiety	Anxiety	23AUG2019	Present
Vitamin D Deficiency	Vitamin D deficiency	22JUN2020	Present
Bilateral temporomandibular joint pain	Temporomandibular joint syndrome	16NOV2020	Present
Right foot pain	Pain in extremity	18DEC2020	Present
Allergy to Vancomycins	Drug hypersensitivity	30DEC2020	Present
Pectus Carinatum	Pectus carinatum	30DEC2020	Present

Study Vaccination(s)			
Vaccination Number	**Vaccine**	**Vaccination Date (Study Day)**	**Time of Vaccination**
1	Placebo	07JAN2021 (1)	09:43

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	Musculoskeletal chest pain	Rib pain on right side	10FEB2021 (35)		10MAR2021 (63)		29

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 (10MAR2021)	NOT RELATED/OTHER: Unknown	1	35	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines		
Investigator Text	**WHO Drug Preferred Term**	**Start Date**
Fluarix Quadrivalent (Influenza Vaccine)	INFLUENZA VACCINE INACT SPLIT 4V	21DEC2020

SARS-COV-2 Baseline Tests - Central Laboratory				
Visit	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
Visit 1	07JAN2021 (1)	07JAN2021 (1)	NASAL_SWAB	POSITIVE
Visit 1	07JAN2021 (1)	07JAN2021 (1)	SERUM	NEGATIVE
Visit 2	17FEB2021 (42)	17FEB2021 (42)	NASAL_SWAB	POSITIVE

Case Details		
Visit	**>7 Days After Dose 2**	**Severe**
COVID Illness Visit 1	No	No
COVID Illness Visit 2	No	No

Signs and Symptoms of Potential COVID-19			
Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing	**Prespecified Event**	**Symptoms (Prespecified and Others)**	**MedDRA Preferred Term**
COVID Illness Visit 1 / 20JAN2021 (14)/ 19JAN2021 (13)/ 20JAN2021 (14)	YES	NEW OR INCREASED SHORTNESS OF BREATH	
COVID Illness Visit 2 / 29JAN2021 (23)/ 26JAN2021 (20)/ 26JAN2021 (20)	YES	DIARRHEA	

Diagnosis of Potential COVID-19 Illness					
Visit	**Visit Date (Study Day)**	**Respiratory Illness Diagnosis**	**Date of Diagnosis (Study Day)**	**Toxicity Grade**	**MedDRA Preferred Term**
COVID Illness Visit 1	20JAN2021 (14)	COVID 19	24JAN2021 (18)	1	COVID-19

SARS-COV-2 Test - Central Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Test Result**
1	COVID Illness Visit 1	20JAN2021 (14)	21JAN2021 (15)	NASAL_SWAB_SELF	POSITIVE
2	COVID Illness Visit 2	29JAN2021 (23)	29JAN2021 (23)	NASAL_SWAB_SELF	POSITIVE

SARS-COV-2 Test - Local Laboratory					
Lab Test Number	**Visit**	**Visit Date (Study Day)**	**Date of Collection (Study Day)**	**Specimen Type**	**Specimen Collection Location**
1	COVID Illness Visit 1	20JAN2021 (14)	24JAN2021 (18)	SWABBED MATERIAL	NASOPHARYNX

SARS-COV-2 Test - Local Laboratory				
Lab Test Number	**Test Result**	**Comments/Findings/Details**	**Trade Name**	**Tradename Other (Specify)**
1	POSITIVE		OTHER	SARS COV2 TEST CLIA CERT LAB

Health Care Utilization

Visit	Visit Date (Study Day)	Physician, Healthcare Professional, or Other Type of Practitioner (Specify)	Occurrence of Visits/Contacts	Number of Visits or Contacts	Other Type of Practitioner (Specify)
COVID Illness Visit 1	20JAN2021 (14)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		TELEPHONE CONSULTATION	NO		NA
		URGENT CARE	NO		NA
COVID Illness Visit 2	29JAN2021 (23)	EMERGENCY ROOM	NO		NA
		OTHER	NO		NA
		PRIMARY CARE PHYSICIAN	NO		NA
		SPECIALIST	NO		NA
		URGENT CARE	NO		NA
		TELEPHONE CONSULTATION	YES	1	NA

Hospitalization Details

No Hospitalization Details

Respiratory Treatment

No Respiratory Treatment

Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction
No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction

Laboratory Results - Clinical Chemistry
No Laboratory Results - Clinical Chemistry

Laboratory Results - Hematology
No Laboratory Results - Hematology

Vital Signs - COVID-19
No Vital Signs - COVID-19

Oxygenation Parameters
No Oxygenation Parameters

Concomitant Medications - Vasopressors
No Concomitant Medications - Vasopressors

Imaging
No Imaging

Subject Summary			
Status	**Study Phase**	**Withdrawal/Completion Date**	**Reason for Withdrawal**
Completed	SCREENING	07JAN2021	
Withdrawn	VACCINATION	26JAN2021	NO LONGER MEETS ELIGIBILITY CRITERIA
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Narrative Comment
Subject C4591001 1270 12701237, a 13-year-old American Indian or Alaska native female with a height of 160 cm, a weight of 69.7 kg, and a BMI of 27.2 kg/m2, received Dose 1 on 07 Jan 2021. The subject had a reported medical history of depression (since 02 Dec 2014), asthma (since 01 Feb 2016), anxiety (since 23 Aug 2019), vitamin D deficiency (since 22 Jun 2020), temporomandibular joint syndrome (since 16 Nov 2020), pain in extremity (right foot; since 18 Dec 2020), and drug hypersensitivity (allergy to vancomycin) and pectus carinatum (both since 30 Dec 2020). The central laboratory SARS-CoV-2 NAAT results were positive at Visit 1 and Visit 2. The central laboratory N-binding antibody result was negative at Visit 1. The subject experienced 2 protocol-defined COVID-19 illnesses. On 24 Jan 2021 (Day 18), the subject was diagnosed with COVID-19 and reported new or increased shortness of breath, with the symptom starting on 19 Jan 2021, 12 days after receiving Dose 1; the symptom resolved on 20 Jan 2021 (Day 14). The central laboratory SARS-CoV-2 NAAT result at the time of the first COVID-19 illness on 21 Jan 2021 (Day 15) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the first COVID-19 illness on 24 Jan 2021 (Day 18) was positive. For the first COVID-19 illness, the subject did not have any contact with nonstudy healthcare personnel. The subject reported diarrhea, with the symptom starting on 26 Jan 2021, 19 days after receiving Dose 1; the symptom resolved on 26 Jan 2021 (Day 20). The central laboratory SARS-CoV-2 NAAT result at the time of the second COVID-19 illness on 29 Jan 2021 (Day 23) was positive. For the second COVID-19 illness, the subject had a telephone consultation (once). The subject was discontinued from the study intervention on 26 Jan 2021 since she no longer met the eligibility criteria and remains in the study to be evaluated for safety, immunogenicity, and efficacy.