COVID-19 Case Strain Sequencing Report

Study C4591001

04 June 2021

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ABBREVIATIONS

Abbreviation	Definition
BLA	Biologics License Application
CDC	(US) Centers for Disease Control and Prevention
cDNA	complimentary DNA
CI	confidence interval
CoV	coronavirus
Ct	cycle threshold
COVID-19	coronavirus disease 2019
DNA	deoxyribonucleic acid
ECMO	extracorporeal membrane oxygenation
EUA	Emergency Use Authorization
FDA	(US) Food and Drug Administration
ICU	intensive care unit
IND application	Investigational New Drug application
NAAT	nucleic acid amplification test
PCR	polymerase chain reaction
RNA	ribonucleic acid
RT-PCR	reverse transcription–polymerase chain reaction
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus-2; virus causing the disease COVID-19
US	United States
VE	vaccine efficacy
VOC	variant of concern
VOI	variant of interest
QNS sample	quantity not sufficient sample

1. BACKGROUND

Reference is made to the Biologics License Application (BLA) 125742 for the COVID-19 vaccine BNT162b2 (BNT162; PF-07302048), which Pfizer and BioNTech are developing, and which is currently available in the United States (US) under Emergency Use Authorization (EUA) 27034 for the prevention of Coronavirus Disease 2019 (COVID-19) in individuals ≥12 years of age. The Investigational New Drug (IND) application was effective on 29 April 2020 and Pfizer initiated the pivotal clinical study (C4591001) in the US on 04 May 2020.

This report provides sequencing data for the SARS-CoV-2 lineages identified among the confirmed COVID-19 cases as of the data cutoff date of 13 March 2021. This same data cutoff date was applied to updated efficacy data included in the BLA, in clinical modules submitted on 06 May 2021, which included the C4591001 6-Month Update Interim Clinical Study Report (Module 5.3.5.1), Summary of Clinical Efficacy (Module 2.7.3), and Clinical Overview (Module 2.5). Sequencing data were not available at the time of the 13 March 2021 submission data cutoff.

2. PHASE 2/3 COVID-19 CASE STRAIN SEQUENCE DATA IN STUDY C4591001

2.1. Analysis Endpoints and Methods

2.1.1. COVID-19 Case Determination and Definitions

Details of vaccine efficacy (VE) data analyses previously submitted are provided in the C4591001 protocol and statistical analysis plan and VE results were reported in the C4591001 6-Month Update Interim Clinical Study Report Section 11.1.2.

The previously submitted efficacy analyses used the same data cutoff date (13 March 2021) as used for the COVID-19 case sequence analysis reported herein. The efficacy analyses were conducted on the evaluable and all-available efficacy populations and included subgroup analyses for cases reported in each country (corresponding to study site locations).

Efficacy endpoints analyzed and reported with the data cutoff date of 13 March 2021, for which corresponding COVID-19 case sequence data are reported herein, include:

- COVID-19 incidence per 1000 person-years of follow-up in participants with or without serological or virological evidence of past SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed ≥7 days after Dose 2 (evaluable efficacy population)

- Severe COVID-19 incidence per 1000 person-years of follow-up in participants with or without evidence of past SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed ≥7 days after Dose 2 (evaluable efficacy population), or confirmed after receiving Dose 1 (Dose 1 all-available population)

COVID-19 case determination and definitions, including those for severe disease, are provided below for reference. Assays used for case determination were described in the Summary of Biopharmaceutic Studies and Associated Analytical Methods (Module 2.7.1).

Case Determination

Participants who developed any potential COVID-19 symptoms listed in the protocol were to contact the site immediately and if confirmed to participate in an in-person or telehealth visit as soon as possible (optimally within 3 days of symptom onset, and at the latest 4 days after symptom resolution). At the visit (or prior to the visit, if a participant utilized a self-swab as permitted per protocol), investigators were to collect clinical information and results from local standard-of-care tests sufficient to confirm a COVID-19 diagnosis.

Investigators were to obtain a nasal swab (mid-turbinate) for testing at a central laboratory using a validated reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; EUA200047/A001) to detect SARS-CoV-2. If the evaluation was conducted by telehealth, the participant was to self-collect a nasal swab and ship for assessment at the central laboratory. A local nucleic acid amplification test (NAAT) result was only acceptable if it met protocol-specified criteria and if a central laboratory result was not available, in which case a local NAAT result could be used if obtained using one of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001).

Prior SARS-CoV-2 infection status was determined by virological testing by NAAT on mid-turbinate swab and serological testing for SARS-CoV-2 N-binding antibodies.

Case Definitions

COVID-19 cases (defined by FDA guidance)[1] were based on SARS-CoV-2 positive test result per central laboratory or local testing facility (using an acceptable test per protocol and if no central laboratory result was available) and presence of at least 1 of the following:

- Fever
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste or smell
- Sore throat
- Diarrhea
- Vomiting

CDC criteria-defined COVID-19 cases could include the following additional symptoms:

- Fatigue
- Headache
- Nasal congestion or runny nose
- Nausea

Severe COVID-19 cases (defined by FDA)[1] included presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness:
  - respiratory rate ≥30 breaths per minute
  - heart rate ≥125 beats per minute
  - SpO_2 ≤93% on room air at sea level or PaO_2/FiO_2 <300 mm Hg
- Respiratory failure:
  - needing high-flow oxygen
  - noninvasive ventilation
  - mechanical ventilation
  - extracorporeal membrane oxygenation (ECMO)
- Evidence of shock:
  - systolic blood pressure <90 mm Hg
  - diastolic blood pressure <60 mm Hg
  - requiring vasopressors
- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to an intensive care unit (ICU)
- Death

Efficacy analysis for severe COVID-19 cases was also conducted using the CDC definition of severe COVID-19 (hospitalization, admission to the ICU, intubation or mechanical ventilation, or death).[2]

2.1.2. COVID-19 Case Strain Sequencing

Sequencing of SARS-CoV-2 viral RNA was performed for confirmed cases of COVID-19 evaluated for efficacy during the Study C4591001 Phase 2/3 blinded placebo-controlled follow-up period up to a data cutoff date of 13 March 2021, as described in Section 2.1.1.

Sequencing analyses methods are described in a SARS-CoV-2 Whole Genome Sequencing Data Collection and Analysis guideline (Module 5.3.1.4) and summarized below.

For determination of SARS-CoV-2 lineage, nucleic acid extraction of mid-turbinate nasal swab specimens was performed using the MagMAX™ Viral/Pathogen Ultra Nucleic Acid Isolation Kit processed on a KingFisher Flex or KingFisher Presto.

SARS-CoV-2 viral genome sequencing was performed using the Ion Torrent and Illumina NextSeq platforms. For the Ion Torrent sequencing platform, the Ion AmpliSeq™ SARS-CoV-2 Research Panel was used, which consists of 2 primer pools: one targets polymerase chain reaction (PCR) amplicons specific to SARS-CoV-2, and the other targets amplicons specific to humans as sample processing controls. Oligonucleotide primers based upon available SARS-CoV-2 nucleotide sequences direct the amplification of the viral genome with amplicons that provide >99% coverage of the SARS-CoV-2 genome (~30 kb). To determine the optimal number of target amplification cycles, SARS-CoV-2 viral RNA content in the nucleic acid purified from the mid-turbinate specimens was quantified using

the TaqMan™ 2019-nCoV Assay Kit v1, the TaqMan™ 2019-nCoV Control Kit v1, and TaqPath™ 1-Step RT-qPCR Master Mix, CG. cDNA was synthesized with the SuperScript VILO cDNA synthesis kit. Libraries were prepared using the Ion AmpliSeq™ Library Kit plus the Ion AmpliSeq™ SARS-CoV-2 Research Panel. Libraries underwent template preparation with Ion Chef. Prepared templates were loaded onto an Ion 530 chip for semiconductor sequencing on the Ion GeneStudio™ S5 plus sequencer according to the manufacturer's instructions. Raw sequencing reads generated by the Ion Torrent sequencer were quality and adaptor trimmed by Ion Torrent Suite, and the resulting reads were then mapped to the complete genome of the SARS-CoV-2 Wuhan-Hu-1 isolate (GenBank accession number MN908947.3) using TMAP 5.14.0. Variant calling was carried out with the Torrent Variant Caller using the BAM file from the mapping of the cleaned sequence reads onto the reference sequence of SARS-CoV-2.

SARS-CoV-2 viral genome sequencing performed with the Illumina NextSeq platform used the AmpliSeq for Illumina SARS-CoV-2 panel of PCR primers to enrich for SARS-CoV-2 in the biological specimen. This was a 2-pool design, one containing SARS-CoV-2 amplicon/primer pairs and the other human-specific amplicons as sample processing controls. Oligonucleotide primers based upon available SARS-CoV-2 nucleotide sequences directed the amplification of overlapping amplicons that cover >99% of the viral genome. Nucleic acid extracted from mid-turbinate specimens was digested with DNase (Invitrogen TURBO DNA-free™ Kit, AM1907), and RNA was purified (Qiagen RNeasy MinElute Cleanup Kit) before cDNA synthesis. Synthesis of cDNA used random sequence primers, after which SARS-CoV-2 amplicons were generated from the cDNA, followed by ligation of Universal Next Generation Sequencing Adaptors to the ends of the amplicons. Amplicon libraries were purified with magnetic beads and loaded onto a flow cell for sequence determination using the Illumina NextSeq instrument. Sequences with (b) (4) coverage across the entire spike gene were advanced for viral lineage assignment. Single nucleotide variants were called using the 'Low Frequency Variant Detection' function (b) (4) (b) (4)

For specimens that did not meet acceptance criteria on one sequencing platform, the sample was repeated on the second platform. If the sequence determined using the second platform met acceptance criteria, a SARS-CoV-2 lineage was assigned. If a lineage could not be assigned by either platform (ie, data did not meet acceptance criteria for either platform) and the Cepheid RT-PCR Ct value for that sample was $\leq$34 for either the N or E gene target, the sample was designated 'indeterminate'. Those samples that did not meet acceptance criteria for both platforms and had low SARS-CoV-2 viral RNA content (ie, Ct values for both the N and E gene targets $\geq$34) were designated 'quantity not sufficient' (QNS).

SARS-CoV-2 lineage assignment was based on Pangolin (b) (4) software, which runs a multinomial logistic regression model trained against lineage assignments based on isolate data from GISAID, a global science initiative established in 2008 that provides open-access to genomics data for influenza and SARS-CoV-2 viruses.

2.2. COVID-19 Case Analysis Results

This section summarizes sequence analysis results for SARS-CoV-2 lineages associated with confirmed COVID-19 cases (data cutoff date: 13 March 2021). VE is summarized for the evaluable efficacy population and country subgroups, as was previously reported (refer to Section 2.1.1). Sequence analysis for all SARS-CoV-2 lineages associated with confirmed COVID-19 cases in the BNT162b2 and placebo groups, including any designated as variants of concern (VOCs) or variants of interest (VOIs),[3,4] are presented in Section 2.2.1, and reported for each country subgroup in Section 2.2.2.

2.2.1. Overall Case Sequence Analysis

In the evaluable efficacy population of individuals with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, evaluation of COVID-19 cases confirmed at least 7 days after Dose 2 and reported up to the data cutoff date of 13 March 2021 yielded an estimated VE of 91.1% (2-sided 95% CI: 88.8%, 93.0%). Similar results were observed for participants without prior evidence of infection before and during the vaccination regimen.

Whole genome sequence analysis of SARS-CoV-2 was performed on nasal swab specimens from COVID-19 cases confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, and is summarized by lineage. Among the determinate and quantifiable sequence results, the most frequently identified lineages in total were B.1.2 (40.3%) and B.1.1.33 (8.4%) (see Table 7).

Sequence data for any VOCs or VOIs associated with COVID-19 cases confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen are summarized by lineage in Table 1. Variants that are not VOC/VOIs were grouped into the 'Other' category.

Few VOCs or VOIs were identified in the BNT162b2 group and were overall more frequently identified in the placebo group than in the BNT162b2 group. Of the VOCs and VOIs that were identified for COVID-19 cases reported as of 13 March 2021, P.2 was the most common lineage: 6/81 cases (7.4%) in the BNT162b2 group and 40/873 cases (4.6%) in the placebo group (Table 1).

Table 1. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

SARS-CoV-2 Lineage[b] (Location of lineage first identified)	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=81) n[c](%)	Placebo (N[a]=873) n[c](%)	Total (N[a]=954) n[c](%)
B.1.1.7 (United Kingdom)	0	3 (0.3)	3 (0.3)
B.1.351 (South Africa)	0	9 (1.0)	9 (0.9)
B.1.427/B.1.429 (USA)	1 (1.2)	23 (2.6)	24 (2.5)
B.1.525 (UK and Nigeria)	0	1 (0.1)	1 (0.1)
B.1.526 (USA)	0	1 (0.1)	1 (0.1)
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	1 (1.2)	1 (0.1)	2 (0.2)
P.2 (Brazil)	6 (7.4)	40 (4.6)	46 (4.8)
P.3 (Philippines)	0	0	0
Other	66 (81.5)	755 (86.5)	821 (86.1)
Unknown[d]	7 (8.6)	33 (3.8)	40 (4.2)
Not sequenced	0	8 (0.9)	8 (0.8)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
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2.2.2. Country Subgroup Case Sequence Analysis

Sequence data were evaluated for all SARS-CoV-2 lineages associated with COVID-19 cases confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen and summarized by lineage and by country (corresponding to study site locations). Among the determinate and quantifiable sequence results, a variety of lineages are represented across country subgroups (see Table 8).

As geography is an important factor in the circulation of lineages designated as VOCs or VOIs, sequence data for any VOCs or VOIs associated with COVID-19 cases confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen are summarized by lineage for each country. SARS-CoV-2 lineages are summarized in Table 2 and described for each country below. Variants that are not VOC/VOIs were grouped into the 'Other' category.

Additionally, for each country, a corresponding summary of estimated VE is provided from the previously conducted efficacy analyses (refer to Section 2.1.1). The estimated VE was determined for each country subgroup for the evaluable efficacy population of individuals with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, in which COVID-19 cases were confirmed at least 7 days after Dose 2 and reported up to the data cutoff date of 13 March 2021. Similar results were observed for participants without prior evidence of infection before and during the vaccination regimen.

Table 2. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a] (Location of lineage first identified)	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
Argentina	B.1.1.7 (United Kingdom)	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.351 (South Africa)	16	0	110	0	126	0
	B.1.427/B.1.429 (USA)	16	0	110	0	126	0
	B.1.525 (UK and Nigeria)	16	0	110	0	126	0
	B.1.526 (USA)	16	0	110	0	126	0
	B.1.616 (France)	16	0	110	0	126	0
	B.1.617 (India)	16	0	110	0	126	0
	B.1.618 (India)	16	0	110	0	126	0
	P.1 (Brazil/Japan)	16	0	110	0	126	0
	P.2 (Brazil)	16	1 (6.3)	110	4 (3.6)	126	5 (4.0)
	P.3 (Philippines)	16	0	110	0	126	0
	Other	16	15 (93.8)	110	102 (92.7)	126	117 (92.9)
	Unknown[d]	16	0	110	3 (2.7)	126	3 (2.4)
	Not sequenced	16	0	110	0	126	0
Brazil	B.1.1.7 (United Kingdom)	14	0	82	0	96	0
	B.1.351 (South Africa)	14	0	82	0	96	0
	B.1.427/B.1.429 (USA)	14	0	82	0	96	0
	B.1.525 (UK and Nigeria)	14	0	82	0	96	0
	B.1.526 (USA)	14	0	82	0	96	0
	B.1.616 (France)	14	0	82	0	96	0
	B.1.617 (India)	14	0	82	0	96	0

Table 2. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a] (Location of lineage first identified)	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
	B.1.618 (India)	14	0	82	0	96	0
	P.1 (Brazil/Japan)	14	1 (7.1)	82	1 (1.2)	96	2 (2.1)
	P.2 (Brazil)	14	5 (35.7)	82	35 (42.7)	96	40 (41.7)
	P.3 (Philippines)	14	0	82	0	96	0
	Other	14	6 (42.9)	82	40 (48.8)	96	46 (47.9)
	Unknown[d]	14	2 (14.3)	82	6 (7.3)	96	8 (8.3)
	Not sequenced	14	0	82	0	96	0
Germany	B.1.1.7 (United Kingdom)	0	0	1	0	1	0
	B.1.351 (South Africa)	0	0	1	0	1	0
	B.1.427/B.1.429 (USA)	0	0	1	0	1	0
	B.1.525 (UK and Nigeria)	0	0	1	0	1	0
	B.1.526 (USA)	0	0	1	0	1	0
	B.1.616 (France)	0	0	1	0	1	0
	B.1.617 (India)	0	0	1	0	1	0
	B.1.618 (India)	0	0	1	0	1	0
	P.1 (Brazil/Japan)	0	0	1	0	1	0
	P.2 (Brazil)	0	0	1	0	1	0
	P.3 (Philippines)	0	0	1	0	1	0
	Other	0	0	1	1 (100.0)	1	1 (100.0)
	Unknown[d]	0	0	1	0	1	0
	Not sequenced	0	0	1	0	1	0
Turkey	B.1.1.7 (United Kingdom)	0	0	6	0	6	0

Table 2. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a] (Location of lineage first identified)	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
	B.1.351 (South Africa)	0	0	6	0	6	0
	B.1.427/B.1.429 (USA)	0	0	6	0	6	0
	B.1.525 (UK and Nigeria)	0	0	6	0	6	0
	B.1.526 (USA)	0	0	6	0	6	0
	B.1.616 (France)	0	0	6	0	6	0
	B.1.617 (India)	0	0	6	0	6	0
	B.1.618 (India)	0	0	6	0	6	0
	P.1 (Brazil/Japan)	0	0	6	0	6	0
	P.2 (Brazil)	0	0	6	0	6	0
	P.3 (Philippines)	0	0	6	0	6	0
	Other	0	0	6	6 (100.0)	6	6 (100.0)
	Unknown[d]	0	0	6	0	6	0
	Not sequenced	0	0	6	0	6	0
USA	B.1.1.7 (United Kingdom)	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.351 (South Africa)	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.427/B.1.429 (USA)	51	1 (2.0)	664	23 (3.5)	715	24 (3.4)
	B.1.525 (UK and Nigeria)	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.526 (USA)	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.616 (France)	51	0	664	0	715	0
	B.1.617 (India)	51	0	664	0	715	0
	B.1.618 (India)	51	0	664	0	715	0
	P.1 (Brazil/Japan)	51	0	664	0	715	0
	P.2 (Brazil)	51	0	664	0	715	0

Table 2. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a] (Location of lineage first identified)	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
	P.3 (Philippines)	51	0	664	0	715	0
	Other	51	45 (88.2)	664	606 (91.3)	715	651 (91.0)
	Unknown[d]	51	5 (9.8)	664	23 (3.5)	715	28 (3.9)
	Not sequenced	51	0	664	8 (1.2)	715	8 (1.1)
South Africa	B.1.1.7 (United Kingdom)	0	0	10	0	10	0
	B.1.351 (South Africa)	0	0	10	8 (80.0)	10	8 (80.0)
	B.1.427/B.1.429 (USA)	0	0	10	0	10	0
	B.1.525 (UK and Nigeria)	0	0	10	0	10	0
	B.1.526 (USA)	0	0	10	0	10	0
	B.1.616 (France)	0	0	10	0	10	0
	B.1.617 (India)	0	0	10	0	10	0
	B.1.618 (India)	0	0	10	0	10	0
	P.1 (Brazil/Japan)	0	0	10	0	10	0
	P.2 (Brazil)	0	0	10	1 (10.0)	10	1 (10.0)
	P.3 (Philippines)	0	0	10	0	10	0
	Other	0	0	10	0	10	0
	Unknown[d]	0	0	10	1 (10.0)	10	1 (10.0)
	Not sequenced	0	0	10	0	10	0

Table 2. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a] (Location of lineage first identified)	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Based on PANGO lineages (cov-lineages.org).
b. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
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(Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq cov 7pd2 cntry eval

Note: VOC/VOI lineages by country are in Table 2, with variants that are not VOCs/VOIs grouped in the 'Other' category; all SARS-CoV-2 lineages by country are in Table 8.

Argentina

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in Argentina was 85.7% (2-sided 95% CI: 75.7%, 92.1%), which included 16 cases in the BNT162b2 group and 110 cases in the placebo group. Only a few cases of VOCs or VOIs were identified (Table 2).

Brazil

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in Brazil was 84.2% (2-sided 95% CI: 71.9%, 91.7%), which included 14 cases in the BNT162b2 group and 82 cases in the placebo group.

The P.2 lineage was almost as prevalent as the 'Other' lineages category (Table 2). The P.2 lineage was identified in 5/14 cases (35.7%) in the BNT162b2 group and 35/82 cases (42.7%) in the placebo group. 'Other' lineages were identified in 6/14 cases (42.9%) in the BNT162b2 group and 40/82 cases (48.8%) in the placebo group. These data indicate high vaccine effectiveness against the P2 variant.

Germany

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in Germany was 100.0% (2-sided 95% CI: -3868.6%, 100.0%), which included 0 cases in the BNT162b2 group and 1 case in the placebo group.

Turkey

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in Turkey was 100.0% (2-sided 95% CI: 22.2%, 100.0%), which included 0 cases in the BNT162b2 group and 6 cases in the placebo group.

United States

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in the US was 92.6% (2-sided 95% CI: 90.2%, 94.6%), which included 51 cases in the BNT162b2 group and 664 cases in the placebo group.

SARS-CoV-2 lineages in the US were most frequently categorized as 'Other': 45/51 cases (88.2%) in the BNT162b2 group and 606/664 cases (91.3%) in the placebo group (Table 2). Of the VOI or VOC categories, the B.1.427/B.1.429 lineage was the most common, with 1/51 cases

(2.0%) in the BNT162b2 group and 23/664 cases (3.5%) in the placebo group, demonstrating high vaccine efficacy against this variant.

South Africa

The estimated VE against confirmed COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection in South Africa was 100.0% (2-sided 95% CI: 56.6%, 100.0%), which included 0 cases in the BNT162b2 group and 10 cases in the placebo group.

The most frequently identified lineage of SARS-CoV-2 in South Africa was the B.1.351 VOC: 8/10 cases (80.0%) (Table 2). All 8 cases were in the placebo group, demonstrating high efficacy against this VOC.

2.3. Severe COVID-19 Case Analysis Results

This section summarizes sequence analysis results for SARS-CoV-2 lineages associated with confirmed severe COVID-19 cases (data cutoff date: 13 March 2021). VE against severe disease is summarized for evaluable and all-available efficacy populations, as was previously reported (refer to Section 2.1.1). Sequence analysis for all SARS-CoV-2 lineages associated with FDA-defined severe cases in the BNT162b2 and placebo groups, including any designated as VOCs or VOIs, is presented in Section 2.3.1, and presented for CDC-defined severe cases in Section 2.3.2.

2.3.1. Case Sequence Analysis for Severe COVID-19 per FDA Definition

Evaluable Efficacy Population (Severe Cases Occurring ≥7 Days After Dose 2)

The estimated VE against confirmed severe COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection, using the FDA definition of severity, was 95.3% (2-sided 95% CI: 70.9%, 99.9%) which included 1 severe case in the BNT162b2 group and 21 severe cases in the placebo group. Similar results were observed for participants without prior evidence of infection.

Sequence data were evaluated for SARS-CoV-2 lineages associated with severe COVID-19 cases (as defined by the FDA) confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen and summarized by lineage. Among the determinate and quantifiable sequence results, the most frequently identified lineages in total were B.1.2 (31.8%) and B.1.1.33 (13.6%) (see Table 9). Very few VOC or VOI category lineages were found in the severe cases (Table 3).

Table 3. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First Severe COVID-19 Occurrence Based on FDA-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b] (Location of lineage first identified)	**BNT162b2 (30 µg) (N[a]=1) n[c](%)**	**Placebo (N[a]=21) n[c](%)**	**Total (N[a]=22) n[c](%)**
B.1.1.7 (United Kingdom)	0	0	0
B.1.351 (South Africa)	0	2 (9.5)	2 (9.1)
B.1.427/B.1.429 (USA)	0	0	0
B.1.525 (UK and Nigeria)	0	0	0
B.1.526 (USA)	0	0	0
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	0	0	0
P.2 (Brazil)	0	0	0
P.3 (Philippines)	0	0	0
Other	1 (100.0)	17 (81.0)	18 (81.8)
Unknown[d]	0	1 (4.8)	1 (4.5)
Not sequenced	0	1 (4.8)	1 (4.5)

Abbreviations: FDA = Food and Drug Administration; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File:
./nda2 unblinded/C4591001 BLA Sequence/adxb seq 7pd2 scov eval

Dose 1 All-Available Efficacy Population (All Severe Cases Occurring after Dose 1)

The estimated VE against confirmed severe COVID-19 occurring after Dose 1, using the FDA definition of severity, was 96.7% (2-sided 95% CI: 80.3%, 99.9%) which included 1 severe case in the BNT162b2 group and 30 severe cases in the placebo group.

Sequence data were evaluated for SARS-CoV-2 lineages associated with severe COVID-19 cases (as defined by the FDA) in the Dose 1 all-available efficacy population who had cases occurring after Dose 1 and summarized by lineage. Among the determinate and quantifiable sequence results, the most frequently identified lineages in total were B.1.2 (35.5%) and B.1.1.33 (12.9%) (see Table 10). Very few VOC or VOI category lineages were found in the severe cases (Table 4).

Table 4. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First Severe COVID-19 Occurrence Based on FDA-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b] (Location of lineage first identified)	**BNT162b2 (30 µg) (N[a]=1) n[c](%)**	**Placebo (N[a]=30) n[c](%)**	**Total (N[a]=31) n[c](%)**
B.1.1.7 (United Kingdom)	0	0	0
B.1.351 (South Africa)	0	2 (6.7)	2 (6.5)
B.1.427/B.1.429 (USA)	0	0	0
B.1.525 (UK and Nigeria)	0	0	0
B.1.526 (USA)	0	0	0
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	0	0	0
P.2 (Brazil)	0	0	0
P.3 (Philippines)	0	0	0
Other	1 (100.0)	26 (86.7)	27 (87.1)
Unknown[d]	0	1 (3.3)	1 (3.2)
Not sequenced	0	1 (3.3)	1 (3.2)

Abbreviations: FDA = Food and Drug Administration; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq d1 scov aai

2.3.2. Case Sequence Analysis for Severe COVID-19 per CDC Definition

Evaluable Efficacy Population (Severe Cases Occurring ≥7 Days After Dose 2)

The estimated VE against confirmed severe COVID-19 occurring at least 7 days after receiving Dose 2 for participants with or without prior evidence of SARS-CoV-2 infection, using the CDC definition of severity, was 100.0% (2-sided 95% CI: 88.0%, 100.0%) which included 0 severe cases in the BNT162b2 group and 32 severe cases in the placebo group. Similar results were observed for participants without prior evidence of infection.

Sequence data were evaluated for all SARS-CoV-2 lineages associated with severe COVID-19 cases (as defined by the CDC) confirmed at least 7 days after Dose 2 in the evaluable efficacy population of study participants with or without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen and summarized by lineage. Among the determinate and quantifiable sequence results, the most frequently identified lineages in total were B.1.2 (25.0%) and B.1.1.33 (15.6%) (see Table 11). Very few VOC or VOI category lineages were found in the severe cases (Table 5).

Table 5. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b] (Location of lineage first identified)	**BNT162b2 (30 µg) (N[a]=0) n[c](%)**	**Placebo (N[a]=32) n[c](%)**	**Total (N[a]=32) n[c](%)**
B.1.1.7 (United Kingdom)	0	0	0
B.1.351 (South Africa)	0	1 (3.1)	1 (3.1)
B.1.427/B.1.429 (USA)	0	0	0
B.1.525 (UK and Nigeria)	0	0	0
B.1.526 (USA)	0	0	0
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	0	0	0
P.2 (Brazil)	0	1 (3.1)	1 (3.1)
P.3 (Philippines)	0	0	0
Other	0	27 (84.4)	27 (84.4)
Unknown[d]	0	2 (6.3)	2 (6.3)
Not sequenced	0	1 (3.1)	1 (3.1)

Abbreviations: CDC = Centers for Disease Control and Prevention; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2_unblinded/C4591001_BLA_Sequence/adxb_seq_7pd2_scov_cdc_eval

Dose 1 All-Available Efficacy Population (All Severe Cases Occurring after Dose 1)

The estimated VE against confirmed severe COVID-19 occurring after Dose 1, using the CDC definition of severity, was 97.8% (2-sided 95% CI: 87.2%, 99.9%) which included 1 severe case in the BNT162b2 group and 45 severe cases in the placebo group.

Sequence data were evaluated for all SARS-CoV-2 lineages associated with severe COVID-19 cases (as defined by the CDC) in the Dose 1 all-available efficacy population who had cases occurring after Dose 1 and summarized by lineage. Among the determinate and quantifiable sequence results, the most frequently identified lineages in total were B.1.2 (26.1%) and B.1.1.33 (13.0%) (see Table 12). Very few VOC or VOI category lineages were found in the severe cases (Table 6).

Table 6. Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b] (Location of lineage first identified)	**BNT162b2 (30 µg) (N[a]=1) n[c](%)**	**Placebo (N[a]=45) n[c](%)**	**Total (N[a]=46) n[c](%)**
B.1.1.7 (United Kingdom)	0	0	0
B.1.351 (South Africa)	0	1 (2.2)	1 (2.2)
B.1.427/B.1.429 (USA)	0	0	0
B.1.525 (UK and Nigeria)	0	0	0
B.1.526 (USA)	0	0	0
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	0	0	0
P.2 (Brazil)	0	1 (2.2)	1 (2.2)
P.3 (Philippines)	0	0	0
Other	1 (100.0)	40 (88.9)	41 (89.1)
Unknown[d]	0	2 (4.4)	2 (4.3)
Not sequenced	0	1 (2.2)	1 (2.2)

Abbreviations: CDC = Centers for Disease Control and Prevention; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (20:13) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2_unblinded/C4591001_BLA_Sequence/adxb_seq_d1_scov_cdc_aai

3. CONCLUSIONS

In the Phase 2/3 part of Study C4591001, during blinded placebo-controlled follow-up through a data cutoff date of 13 March 2021, confirmed COVID-19 cases were evaluated in an updated efficacy analysis encompassing up to 6 months of follow-up after participants received Dose 2.

Sequence analysis indicates that VOCs and VOIs were circulating during the surveillance period, and those identified among the confirmed COVID-19 cases in Study C4591001 mostly occurred in the placebo group with few occurring in the BNT162b2 group, for cases reported at least 7 days after receiving the second dose of BNT162b2. The distribution of identified VOCs and VOIs varied by country; however, the estimated VE was high regardless of geography.

COVID-19 cases considered as severe, defined by either FDA or CDC criteria, were comprised predominantly of SARS-CoV-2 lineages that are not designated as VOCs or VOIs, with few identified VOCs or VOIs in the placebo group and none in BNT162b2 group, for severe cases reported at least 7 days after receiving the second dose of BNT162b2. A similar trend was observed for severe cases (per FDA or CDC definition) reported from Dose 1 onwards.

The sequence data confirm vaccine efficacy against more prevalent VOCs/VOIs, such as B.1.351, P.2, and B.1.427/B.1.429. In summary, there is no apparent SARS-CoV-2 lineage pattern among vaccine breakthrough cases that would suggest meaningfully reduced BNT162b2 efficacy against any variant.

4. ADDITIONAL TABLES, LISTINGS, AND FIGURES

4.1. Listings

The following C4591001 BLA Sequence Listings are located in Module 5.3.5.1:

16.2.8.6 Listing of Subjects and SARS-CoV-2 Variants With First COVID-19 Occurrence From 7 Days After Dose 2 and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Evaluable Efficacy (7 Days) Population

16.2.8.7 Listing of Subjects and SARS-CoV-2 Variants With Multiple COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

16.2.8.8 Listing of Subjects and SARS-CoV-2 Variants With First Severe COVID-19 Occurrence Based on CDC-Defined or FDA-Defined Symptoms After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

4.2. Tables

4.2.1. COVID-19 Case Analysis

Table 7. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=81) n[c](%)	Placebo (N[a]=873) n[c](%)	Total (N[a]=954) n[c](%)
A.2	0	1 (0.1)	1 (0.1)
A.2.4	1 (1.2)	1 (0.1)	2 (0.2)
B	0	1 (0.1)	1 (0.1)
B.1	3 (3.7)	65 (7.4)	68 (7.1)
B.1.1	1 (1.2)	2 (0.2)	3 (0.3)
B.1.1.1	1 (1.2)	4 (0.5)	5 (0.5)
B.1.1.105	0	1 (0.1)	1 (0.1)
B.1.1.120	0	1 (0.1)	1 (0.1)
B.1.1.122	0	1 (0.1)	1 (0.1)
B.1.1.139	0	1 (0.1)	1 (0.1)
B.1.1.143	3 (3.7)	5 (0.6)	8 (0.8)
B.1.1.152	0	1 (0.1)	1 (0.1)
B.1.1.161	0	1 (0.1)	1 (0.1)
B.1.1.200	0	1 (0.1)	1 (0.1)
B.1.1.207	0	2 (0.2)	2 (0.2)
B.1.1.220	0	3 (0.3)	3 (0.3)
B.1.1.222	3 (3.7)	11 (1.3)	14 (1.5)
B.1.1.231	0	1 (0.1)	1 (0.1)
B.1.1.244	0	3 (0.3)	3 (0.3)
B.1.1.253	0	1 (0.1)	1 (0.1)
B.1.1.28	1 (1.2)	18 (2.1)	19 (2.0)
B.1.1.285	0	1 (0.1)	1 (0.1)
B.1.1.289	0	1 (0.1)	1 (0.1)
B.1.1.29	2 (2.5)	8 (0.9)	10 (1.0)
B.1.1.291	0	1 (0.1)	1 (0.1)
B.1.1.304	0	1 (0.1)	1 (0.1)
B.1.1.33	10 (12.3)	70 (8.0)	80 (8.4)
B.1.1.34	0	4 (0.5)	4 (0.4)
B.1.1.35	1 (1.2)	1 (0.1)	2 (0.2)
B.1.1.4	0	1 (0.1)	1 (0.1)
B.1.1.44	0	1 (0.1)	1 (0.1)
B.1.1.54	0	1 (0.1)	1 (0.1)
B.1.1.63	0	1 (0.1)	1 (0.1)

Table 7. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=81) n[c](%)	Placebo (N[a]=873) n[c](%)	Total (N[a]=954) n[c](%)
B.1.1.7	0	3 (0.3)	3 (0.3)
B.1.1.70	1 (1.2)	0	1 (0.1)
B.1.1.94	1 (1.2)	0	1 (0.1)
B.1.110.3	0	3 (0.3)	3 (0.3)
B.1.119	0	1 (0.1)	1 (0.1)
B.1.139	1 (1.2)	8 (0.9)	9 (0.9)
B.1.142	0	1 (0.1)	1 (0.1)
B.1.177	0	3 (0.3)	3 (0.3)
B.1.182	0	1 (0.1)	1 (0.1)
B.1.189	0	2 (0.2)	2 (0.2)
B.1.2	24 (29.6)	360 (41.2)	384 (40.3)
B.1.210	1 (1.2)	1 (0.1)	2 (0.2)
B.1.215	0	1 (0.1)	1 (0.1)
B.1.232	0	1 (0.1)	1 (0.1)
B.1.234	2 (2.5)	24 (2.7)	26 (2.7)
B.1.235	0	1 (0.1)	1 (0.1)
B.1.239	0	2 (0.2)	2 (0.2)
B.1.240	1 (1.2)	13 (1.5)	14 (1.5)
B.1.241	1 (1.2)	0	1 (0.1)
B.1.243	1 (1.2)	18 (2.1)	19 (2.0)
B.1.265	1 (1.2)	3 (0.3)	4 (0.4)
B.1.280	0	3 (0.3)	3 (0.3)
B.1.302	0	1 (0.1)	1 (0.1)
B.1.306	0	1 (0.1)	1 (0.1)
B.1.311	1 (1.2)	11 (1.3)	12 (1.3)
B.1.324	0	2 (0.2)	2 (0.2)
B.1.349	0	5 (0.6)	5 (0.5)
B.1.351	0	9 (1.0)	9 (0.9)
B.1.361	0	11 (1.3)	11 (1.2)
B.1.366	0	1 (0.1)	1 (0.1)
B.1.369	0	8 (0.9)	8 (0.8)
B.1.375	0	1 (0.1)	1 (0.1)
B.1.395	0	1 (0.1)	1 (0.1)
B.1.396	0	1 (0.1)	1 (0.1)
B.1.399	1 (1.2)	0	1 (0.1)
B.1.400	0	7 (0.8)	7 (0.7)
B.1.403	0	2 (0.2)	2 (0.2)

Table 7. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=81) n[c](%)	Placebo (N[a]=873) n[c](%)	Total (N[a]=954) n[c](%)
B.1.404	0	9 (1.0)	9 (0.9)
B.1.405	0	1 (0.1)	1 (0.1)
B.1.409	1 (1.2)	2 (0.2)	3 (0.3)
B.1.413	0	1 (0.1)	1 (0.1)
B.1.427	1 (1.2)	5 (0.6)	6 (0.6)
B.1.428	1 (1.2)	1 (0.1)	2 (0.2)
B.1.429	0	18 (2.1)	18 (1.9)
B.1.438	0	2 (0.2)	2 (0.2)
B.1.443	0	1 (0.1)	1 (0.1)
B.1.499	1 (1.2)	17 (1.9)	18 (1.9)
B.1.509	0	4 (0.5)	4 (0.4)
B.1.511	1 (1.2)	0	1 (0.1)
B.1.517	0	2 (0.2)	2 (0.2)
B.1.525	0	1 (0.1)	1 (0.1)
B.1.526	0	1 (0.1)	1 (0.1)
B.47	0	2 (0.2)	2 (0.2)
N.1	0	1 (0.1)	1 (0.1)
N.3	0	1 (0.1)	1 (0.1)
P.1	1 (1.2)	1 (0.1)	2 (0.2)
P.2	6 (7.4)	40 (4.6)	46 (4.8)
Unknown[d]	7 (8.6)	33 (3.8)	40 (4.2)
Not sequenced	0	8 (0.9)	8 (0.8)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq var cov 7pd2 eval

Table 8. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a]	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
Argentina	B.1	16	1 (6.3)	110	12 (10.9)	126	13 (10.3)
	B.1.1.1	16	1 (6.3)	110	3 (2.7)	126	4 (3.2)
	B.1.1.200	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.1.28	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.1.289	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.1.291	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.1.33	16	8 (50.0)	110	62 (56.4)	126	70 (55.6)
	B.1.1.35	16	1 (6.3)	110	1 (0.9)	126	2 (1.6)
	B.1.1.7	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.1.70	16	1 (6.3)	110	0	126	1 (0.8)
	B.1.2	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.302	16	0	110	1 (0.9)	126	1 (0.8)
	B.1.428	16	1 (6.3)	110	0	126	1 (0.8)
	B.1.499	16	1 (6.3)	110	17 (15.5)	126	18 (14.3)
	B.1.511	16	1 (6.3)	110	0	126	1 (0.8)
	N.3	16	0	110	1 (0.9)	126	1 (0.8)
	P.2	16	1 (6.3)	110	4 (3.6)	126	5 (4.0)
	Unknown[d]	16	0	110	3 (2.7)	126	3 (2.4)
Brazil	B.1	14	0	82	3 (3.7)	96	3 (3.1)
	B.1.1.1	14	0	82	1 (1.2)	96	1 (1.0)
	B.1.1.143	14	2 (14.3)	82	4 (4.9)	96	6 (6.3)
	B.1.1.28	14	1 (7.1)	82	17 (20.7)	96	18 (18.8)
	B.1.1.33	14	2 (14.3)	82	8 (9.8)	96	10 (10.4)
	B.1.1.34	14	0	82	4 (4.9)	96	4 (4.2)
	B.1.1.44	14	0	82	1 (1.2)	96	1 (1.0)
	B.1.1.94	14	1 (7.1)	82	0	96	1 (1.0)
	B.1.182	14	0	82	1 (1.2)	96	1 (1.0)
	N.1	14	0	82	1 (1.2)	96	1 (1.0)
	P.1	14	1 (7.1)	82	1 (1.2)	96	2 (2.1)
	P.2	14	5 (35.7)	82	35 (42.7)	96	40 (41.7)
	Unknown[d]	14	2 (14.3)	82	6 (7.3)	96	8 (8.3)
Germany	B.1.177	0	0	1	1 (100.0)	1	1 (100.0)
Turkey	B.1	0	0	6	1 (16.7)	6	1 (16.7)

Table 8. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a]	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
	B.1.1.105	0	0	6	1 (16.7)	6	1 (16.7)
	B.1.1.120	0	0	6	1 (16.7)	6	1 (16.7)
	B.1.1.29	0	0	6	1 (16.7)	6	1 (16.7)
	B.1.1.54	0	0	6	1 (16.7)	6	1 (16.7)
	B.1.177	0	0	6	1 (16.7)	6	1 (16.7)
USA	A.2	51	0	664	1 (0.2)	715	1 (0.1)
	A.2.4	51	1 (2.0)	664	1 (0.2)	715	2 (0.3)
	B	51	0	664	1 (0.2)	715	1 (0.1)
	B.1	51	2 (3.9)	664	49 (7.4)	715	51 (7.1)
	B.1.1	51	1 (2.0)	664	2 (0.3)	715	3 (0.4)
	B.1.1.122	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.139	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.143	51	1 (2.0)	664	1 (0.2)	715	2 (0.3)
	B.1.1.152	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.161	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.207	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.1.220	51	0	664	3 (0.5)	715	3 (0.4)
	B.1.1.222	51	3 (5.9)	664	11 (1.7)	715	14 (2.0)
	B.1.1.231	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.244	51	0	664	3 (0.5)	715	3 (0.4)
	B.1.1.253	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.285	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.29	51	2 (3.9)	664	7 (1.1)	715	9 (1.3)
	B.1.1.304	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.4	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.63	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.1.7	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.110.3	51	0	664	3 (0.5)	715	3 (0.4)
	B.1.119	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.139	51	1 (2.0)	664	8 (1.2)	715	9 (1.3)
	B.1.142	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.177	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.189	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.2	51	24 (47.1)	664	359 (54.1)	715	383 (53.6)
	B.1.210	51	1 (2.0)	664	1 (0.2)	715	2 (0.3)
	B.1.215	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.232	51	0	664	1 (0.2)	715	1 (0.1)

Table 8. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a]	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
	B.1.234	51	2 (3.9)	664	24 (3.6)	715	26 (3.6)
	B.1.235	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.239	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.240	51	1 (2.0)	664	13 (2.0)	715	14 (2.0)
	B.1.241	51	1 (2.0)	664	0	715	1 (0.1)
	B.1.243	51	1 (2.0)	664	18 (2.7)	715	19 (2.7)
	B.1.265	51	1 (2.0)	664	3 (0.5)	715	4 (0.6)
	B.1.280	51	0	664	3 (0.5)	715	3 (0.4)
	B.1.306	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.311	51	1 (2.0)	664	11 (1.7)	715	12 (1.7)
	B.1.324	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.349	51	0	664	5 (0.8)	715	5 (0.7)
	B.1.351	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.361	51	0	664	11 (1.7)	715	11 (1.5)
	B.1.366	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.369	51	0	664	8 (1.2)	715	8 (1.1)
	B.1.375	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.395	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.396	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.399	51	1 (2.0)	664	0	715	1 (0.1)
	B.1.400	51	0	664	7 (1.1)	715	7 (1.0)
	B.1.403	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.404	51	0	664	9 (1.4)	715	9 (1.3)
	B.1.405	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.409	51	1 (2.0)	664	2 (0.3)	715	3 (0.4)
	B.1.413	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.427	51	1 (2.0)	664	5 (0.8)	715	6 (0.8)
	B.1.428	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.429	51	0	664	18 (2.7)	715	18 (2.5)
	B.1.438	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.443	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.509	51	0	664	4 (0.6)	715	4 (0.6)
	B.1.517	51	0	664	2 (0.3)	715	2 (0.3)
	B.1.525	51	0	664	1 (0.2)	715	1 (0.1)
	B.1.526	51	0	664	1 (0.2)	715	1 (0.1)
	B.47	51	0	664	2 (0.3)	715	2 (0.3)
	Unknown[d]	51	5 (9.8)	664	23 (3.5)	715	28 (3.9)
	Not sequenced	51	0	664	8 (1.2)	715	8 (1.1)

Table 8. Summary of SARS-CoV-2 Variants for the First COVID-19 Occurrence From 7 Days After Dose 2, by Country – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)		Placebo		Total	
Country	SARS-CoV-2 Lineage[a]	N[b]	n[c](%)	N[b]	n[c](%)	N[b]	n[c](%)
South Africa	B.1.351	0	0	10	8 (80.0)	10	8 (80.0)
	P.2	0	0	10	1 (10.0)	10	1 (10.0)
	Unknown[d]	0	0	10	1 (10.0)	10	1 (10.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Based on PANGO lineages (cov-lineages.org).
b. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq var cov 7pd2 cntry eval

4.2.2. Severe COVID-19 Analysis

Table 9. Summary of SARS-CoV-2 Variants for the First Severe COVID-19 Occurrence Based on FDA-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=21)	Total (N[a]=22)
SARS-CoV-2 Lineage[b]	n[c](%)	n[c](%)	n[c](%)
B.1.1.143	0	1 (4.8)	1 (4.5)
B.1.1.291	0	1 (4.8)	1 (4.5)
B.1.1.33	0	3 (14.3)	3 (13.6)
B.1.1.94	1 (100.0)	0	1 (4.5)
B.1.2	0	7 (33.3)	7 (31.8)
B.1.280	0	1 (4.8)	1 (4.5)
B.1.351	0	2 (9.5)	2 (9.1)
B.1.361	0	2 (9.5)	2 (9.1)
B.1.409	0	1 (4.8)	1 (4.5)
B.1.413	0	1 (4.8)	1 (4.5)
Unknown[d]	0	1 (4.8)	1 (4.5)
Not sequenced	0	1 (4.8)	1 (4.5)

Abbreviations: FDA = Food and Drug Administration; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (21:12) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq var 7pd2 scov eval

Table 10. Summary of SARS-CoV-2 Variants for the First Severe COVID-19 Occurrence Based on FDA-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=1) n[c](%)	Placebo (N[a]=30) n[c](%)	Total (N[a]=31) n[c](%)
B.1	0	1 (3.3)	1 (3.2)
B.1.1.143	0	1 (3.3)	1 (3.2)
B.1.1.162	0	1 (3.3)	1 (3.2)
B.1.1.291	0	1 (3.3)	1 (3.2)
B.1.1.33	0	4 (13.3)	4 (12.9)
B.1.1.94	1 (100.0)	0	1 (3.2)
B.1.2	0	11 (36.7)	11 (35.5)
B.1.234	0	1 (3.3)	1 (3.2)
B.1.237	0	1 (3.3)	1 (3.2)
B.1.280	0	1 (3.3)	1 (3.2)
B.1.351	0	2 (6.7)	2 (6.5)
B.1.361	0	2 (6.7)	2 (6.5)
B.1.409	0	1 (3.3)	1 (3.2)
B.1.413	0	1 (3.3)	1 (3.2)
Unknown[d]	0	1 (3.3)	1 (3.2)
Not sequenced	0	1 (3.3)	1 (3.2)

Abbreviations: FDA = Food and Drug Administration; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (21:12) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2 unblinded/C4591001 BLA Sequence/adxb seq var d1 scov aai

Table 11. Summary of SARS-CoV-2 Variants for the First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=0) n[c](%)	Placebo (N[a]=32) n[c](%)	Total (N[a]=32) n[c](%)
B	0	1 (3.1)	1 (3.1)
B.1	0	4 (12.5)	4 (12.5)
B.1.1.122	0	1 (3.1)	1 (3.1)
B.1.1.200	0	1 (3.1)	1 (3.1)
B.1.1.291	0	1 (3.1)	1 (3.1)
B.1.1.33	0	5 (15.6)	5 (15.6)
B.1.2	0	8 (25.0)	8 (25.0)
B.1.280	0	1 (3.1)	1 (3.1)
B.1.351	0	1 (3.1)	1 (3.1)
B.1.361	0	2 (6.3)	2 (6.3)
B.1.404	0	1 (3.1)	1 (3.1)
B.1.409	0	1 (3.1)	1 (3.1)
B.1.499	0	1 (3.1)	1 (3.1)
P.2	0	1 (3.1)	1 (3.1)
Unknown[d]	0	2 (6.3)	2 (6.3)
Not sequenced	0	1 (3.1)	1 (3.1)

Abbreviations: CDC = Centers for Disease Control and Prevention; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2_unblinded/C4591001_BLA_Sequence/adxb_seq_var_7pd2_scov_cdc_eval

Table 12. Summary of SARS-CoV-2 Variants for the First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b]	BNT162b2 (30 µg) (N[a]=1) n[c](%)	Placebo (N[a]=45) n[c](%)	Total (N[a]=46) n[c](%)
A	0	1 (2.2)	1 (2.2)
B	0	1 (2.2)	1 (2.2)
B.1	0	5 (11.1)	5 (10.9)
B.1.1.122	0	1 (2.2)	1 (2.2)
B.1.1.162	0	1 (2.2)	1 (2.2)
B.1.1.200	0	1 (2.2)	1 (2.2)
B.1.1.291	0	1 (2.2)	1 (2.2)
B.1.1.33	0	6 (13.3)	6 (13.0)
B.1.2	0	12 (26.7)	12 (26.1)
B.1.237	0	1 (2.2)	1 (2.2)
B.1.241	0	1 (2.2)	1 (2.2)
B.1.280	0	1 (2.2)	1 (2.2)
B.1.306	1 (100.0)	0	1 (2.2)
B.1.351	0	1 (2.2)	1 (2.2)
B.1.361	0	2 (4.4)	2 (4.3)
B.1.404	0	1 (2.2)	1 (2.2)
B.1.409	0	1 (2.2)	1 (2.2)
B.1.448	0	1 (2.2)	1 (2.2)
B.1.452	0	1 (2.2)	1 (2.2)
B.1.499	0	1 (2.2)	1 (2.2)
N.3	0	1 (2.2)	1 (2.2)
P.2	0	1 (2.2)	1 (2.2)
Unknown[d]	0	2 (4.4)	2 (4.3)
Not sequenced	0	1 (2.2)	1 (2.2)

Abbreviations: CDC = Centers for Disease Control and Prevention; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first severe COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.
PFIZER CONFIDENTIAL SDTM Creation: 01JUN2021 (17:11) Source Data: adxb Table Generation: 01JUN2021 (18:36) (Cutoff Date: 13MAR2021, Snapshot Date: 28MAY2021) Output File: ./nda2_unblinded/C4591001_BLA_Sequence/adxb_seq_var_d1_scov_cdc_aai

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Document Approval Record

Document Name:	C4591001 COVID-19 Case Sequencing Data Ad Hoc Report for BLA
Document Title:	C4591001 COVID-19 Case Sequencing Data Ad Hoc Report for BLA

Signed By:	Date(GMT)	Signing Capacity
Perez, John	04-Jun-2021 14:56:38	Final Approval