

**16.2.8.1.1 Listing of Subjects With First Severe COVID-19 Occurrence After Dose 1
– Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period
– Dose 1 All-Available Efficacy Population – CDC+Protocol**

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day^a	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs, Symptoms, and Events	SARS-CoV-2 NAAT Result (Central Lab/Local Lab^b), Swab Date	Protocol/CDC Defined Symptoms
No subject meets the reporting criteria.								
<p>Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2. Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.</p> <p>a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1. b. SARS-CoV-2 NAAT results from the local lab are based on the Cepheid Xpert[®] Xpress SARS-CoV-2 test, Roche cobas[®] SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 27MAR2021 (01:55) Source Data: adsympt Table Generation: 02APR2021 (10:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt 1001_sym_sev_d1_aai_ped</p>								

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
						N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT		
C4591001 1006 10061206 (USA/12/M)*	Placebo	Dose 2/10	01JAN2021	03JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 01JAN2021
C4591001 1006 10061259 (USA/15/F)	Placebo	Dose 2/7	11JAN2021	24JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 18JAN2021
C4591001 1006 10061260 (USA/12/F)*	Placebo	Dose 2/17	21JAN2021	27JAN2021	Neg	Neg/Neg/Neg	New or increased cough Sore throat	Pos/, 21JAN2021
C4591001 1006 10061284 (USA/14/M)	Placebo	Dose 2/8	15JAN2021	16JAN2021	Neg	Neg/Neg/Pos	Diarrhea	Pos/, 18JAN2021
C4591001 1007 10071409 (USA/13/M)	BNT162b2 (30 µg)	Dose 1/10	31OCT2020	04NOV2020	Neg	Neg/Neg/Neg	Fever	Pos/, 02NOV2020
C4591001 1007 10071505 (USA/12/F)	Placebo	Dose 2/2	29DEC2020	08JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell	Pos/, 03JAN2021
C4591001 1007 10071527 (USA/12/M)	Placebo	Dose 2/10	07JAN2021	10JAN2021	Neg	Neg/Neg/Pos	Sore throat	Pos/Pos, 10JAN2021
C4591001 1007 10071559 (USA/14/F)*	Placebo	Dose 2/11	14JAN2021	26JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 15JAN2021
							Sore throat	

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16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1007 10071603 (USA/13/M)*	Placebo	Dose 2/35	22FEB2021	28FEB2021	Neg	Neg/Neg/Neg	Fever	Pos/, 23FEB2021
C4591001 1007 10071622 (USA/15/M)	BNT162b2 (30 µg)	Dose 1/2	31DEC2020	15FEB2021	Neg	Neg/Neg/Neg	New loss of taste or smell Sore throat	Pos/, 04JAN2021
C4591001 1007 10071642 (USA/15/M)	BNT162b2 (30 µg)	Dose 1/7	10JAN2021	20JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell New or increased cough	Pos/, 12JAN2021
C4591001 1008 10081871 (USA/14/F)	Placebo	Dose 1/14	12JAN2021	19JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 18JAN2021
C4591001 1008 10081884 (USA/15/F)	Placebo	Dose 1/19	18JAN2021	26JAN2021	Neg	Neg/Neg/Pos	Sore throat Sore throat	Pos/, 20JAN2021
C4591001 1009 10091208 (USA/15/M)*	Placebo	Dose 2/66	10JAN2021	14JAN2021	Neg	Neg/Neg/Neg	New or increased cough New or increased shortness of breath	Pos/, 10JAN2021

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– Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population**

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1009 10091282 (USA/14/M)*	Placebo	Dose 2/42	01FEB2021	02FEB2021	Neg	Neg/Neg/Neg	New or increased muscle pain Sore throat Chills	Pos/, 02FEB2021
C4591001 1009 10091338 (USA/15/F)	Placebo	Dose 1/19	01JAN2021	24FEB2021	Neg	Neg/Neg/Pos	New or increased muscle pain New loss of taste or smell Sore throat Fever	Pos/, 02JAN2021
C4591001 1009 10091366 (USA/14/F)	Placebo	Dose 1/9	25DEC2020	01JAN2021	Neg	Neg/Neg/Pos	New or increased cough New or increased muscle pain Sore throat Fever	Pos/, 28DEC2020
							Chills New or increased muscle pain Sore throat	

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Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result
								(Central Lab/Local Lab ^b), Swab Date
C4591001 1009 10091412 (USA/15/M)*	Placebo	Dose 2/29	01MAR2021		Neg	Neg/Neg/Neg	New or increased cough	Pos/, 01MAR2021
C4591001 1016 10161316 (USA/15/M)	Placebo	Dose 1/17	01NOV2020	11NOV2020	Neg	Neg/Neg/Pos	Sore throat New or increased cough	Pos/, 02NOV2020
C4591001 1016 10161319 (USA/12/F)	Placebo	Dose 2/6	09NOV2020	20NOV2020	Neg	Neg/Neg/Neg	Chills New or increased muscle pain New loss of taste or smell Sore throat Diarrhea	Pos/, 10NOV2020
C4591001 1016 10161379 (USA/13/M)	Placebo	Dose 1/13	19JAN2021	02FEB2021	Neg	Neg/Neg/Neg	New or increased cough Chills New loss of taste or smell Sore throat	Pos/ (R1 Pos), 19JAN2021 (29JAN2021)
							New loss of taste or smell	

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– Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population**

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1039 10391268 (USA/13/F)*	Placebo	Dose 2/33	29JAN2021	03MAR2021	Neg	Neg/Neg/Neg	Sore throat Fever	Pos/, 29JAN2021
C4591001 1044 10441264 (USA/14/F)	Placebo	Dose 2/6	02JAN2021		Neg	Neg/Neg/Neg	New or increased cough New or increased shortness of breath Chills New or increased muscle pain	Pos/, 04JAN2021
C4591001 1044 10441374 (USA/15/M)*	Placebo	Dose 2/13	14FEB2021	17FEB2021	Neg	Neg/Neg/Neg	Sore throat Chills	Pos/, 16FEB2021
C4591001 1057 10571428 (USA/14/M)	Placebo	Dose 1/5	28DEC2020	02JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell Vomiting Fever	Pos/, 29DEC2020
							Chills Sore throat	

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Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
						N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT		
C4591001 1091 10911404 (USA/13/F)*	Placebo	Dose 2/27	23JAN2021		Neg	Neg/Neg/Neg	New or increased shortness of breath Chills New or increased muscle pain New loss of taste or smell Sore throat Diarrhea	Pos/, 25JAN2021
C4591001 1091 10911407 (USA/12/M)	Placebo	Dose 2/6	02JAN2021	16JAN2021	Neg	Neg/Neg/Neg	New or increased cough New or increased muscle pain Diarrhea	Pos/, 06JAN2021
C4591001 1123 11231501 (USA/12/F)	Placebo	Dose 1/18	14JAN2021	02FEB2021	Neg	Neg/Neg/Neg	Fever New or increased cough New or increased muscle pain New loss of taste or smell Sore throat	Pos/, 19JAN2021

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Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1	Signs and Symptoms	SARS-CoV-2
						N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT		NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1126 11261287 (USA/15/M)	Placebo	Dose 1/15	30DEC2020	11JAN2021	Neg	Neg/Neg/Pos	Fever	Pos/, 04JAN2021
C4591001 1142 11421388 (USA/15/M)*	Placebo	Dose 2/25	19FEB2021		Neg	Neg/Neg/Neg	Sore throat	Pos/, 19FEB2021
C4591001 1147 11471280 (USA/12/M)	Placebo	Dose 1/6	09JAN2021	12JAN2021	Neg	Neg/Neg/Unk	Fever	Pos/, 10JAN2021
C4591001 1150 11501204 (USA/14/M)*	Placebo	Dose 2/32	04FEB2021		Neg	Neg/Neg/Neg	Chills New or increased cough	Pos/, 05FEB2021
C4591001 1150 11501291 (USA/15/M)	Placebo	Dose 1/2	12JAN2021	26JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 13JAN2021
C4591001 1152 11521666 (USA/15/F)*	Placebo	Dose 2/17	15JAN2021	23JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 21JAN2021
C4591001 1156 11561260 (USA/15/F)*	Placebo	Dose 2/82	01FEB2021	05FEB2021	Neg	Neg/Neg/Neg	New or increased muscle pain New loss of taste or smell New or increased muscle pain	Pos/, 01FEB2021

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						N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT		
C4591001 1156 11561263 (USA/15/M)*	Placebo	Dose 2/41	20DEC2020	25DEC2020	Neg	Neg/Neg/Neg	New or increased cough	Pos/, 22DEC2020
C4591001 1235 12351243 (USA/15/M)*	Placebo	Dose 2/42	09FEB2021	11FEB2021	Neg	Neg/Neg/Neg	New or increased cough Sore throat Diarrhea	Pos/, 11FEB2021
C4591001 1270 12701237 (USA/13/F)	Placebo	Dose 1/13	19JAN2021	20JAN2021	Pos	Neg/Pos/Pos	New or increased shortness of breath	Pos/, 21JAN2021

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; Neg = negative; Pos = positive; R1 = repeat central swab 1; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Unk = unknown.
 Note: * indicates subject in the evaluable efficacy (7 days) population with first COVID-19 occurrence from 7 days after Dose 2 and without evidence of infection prior to 7 days after Dose 2.
 Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.
 a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1.
 b. SARS-CoV-2 NAAT results from the local lab are based on the Cepheid Xpert[®] Xpress SARS-CoV-2 test, Roche cobas[®] SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.
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