Safety & Immunogenicity Booster (3rd) Dose BNT162b2 (10 µg) 5 to <12 y olds Study C4591007

Charu Sabharwal, MD, MPH
Pfizer, Director
Vaccine Clinical
Research & Development

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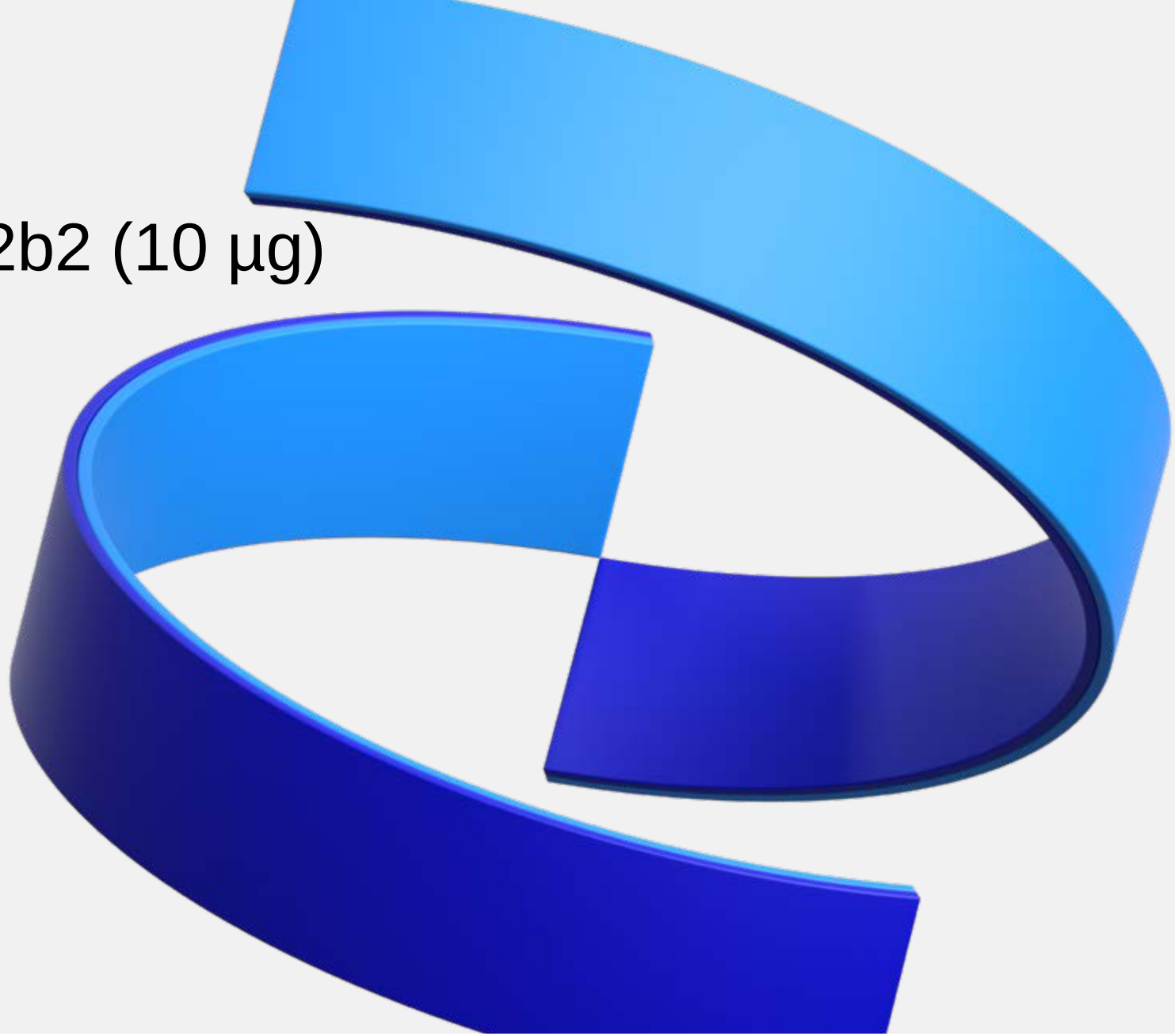


Booster Dose: 5 to <12 years Phase 2/3 BNT162b2 10 µg
Safety and Immunogenicity Assessments
Data as Agreed Upon with the FDA

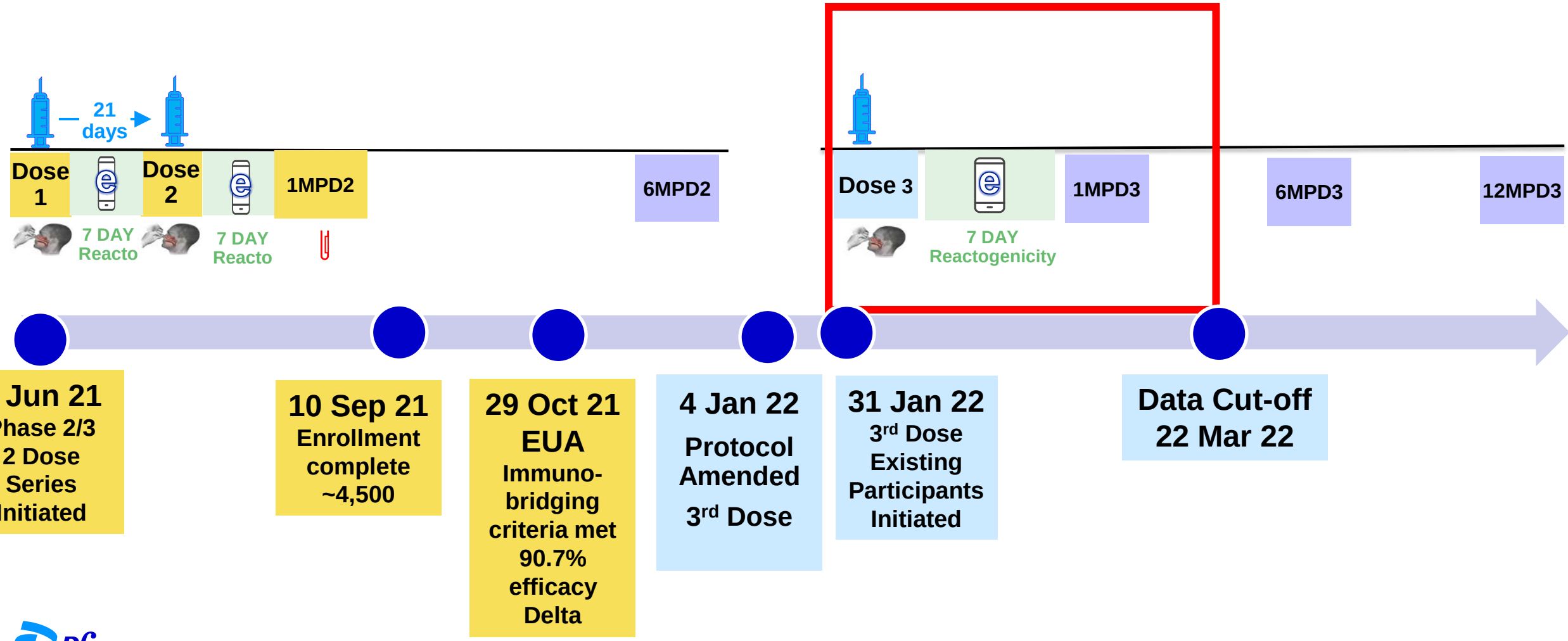
Safety and Tolerability

- 401 participants with follow-up from Dose 3 to 1-month post-Dose 3

Immunogenicity

- Subset of 130 participants
  - Completed 1MPD3
  - Immune responses against SARS-CoV-2 wild type
    - Additional 67 participants from Dose 2 evaluable population included for 1MPD2 comparison
- From the 130 participants above, 30 participants immune responses against the Omicron variant

Study Design and Timelines: 5 to <12 Years of Age BNT162b2 10 mcg



- EUA= Emergency Use Authorization

Demography for 5 to <12 -year olds Who Received Dose 3 of BNT162b2 Overall, representative of C4591007 participants

		BNT162b2 (10µg) (N=401) n (%)
Sex	Male	210 (52.4)
	Female	191 (47.6)
Race	White	281 (70.1)
	Black or African American	29 (7.2)
	American Indian or Alaska native	8 (2.0)
	Asian	31 (7.7)
	Multiracial	46 (11.5)
Ethnicity	Hispanic/Latino	92 (22.9)
	Non-Hispanic/non-Latino	306 (76.3)
Age at vaccination (Dose 1)	Mean (SD)	7.9 (1.75)
	Min, Max	(5, 11)
Obese	Yes	39 (9.7)
Comorbidities[a]	Yes	119 (29.7)
History of COVID-19	Yes	0 (0%)
Baseline (Dose 1) positive for SARS CoV-2	Yes	22 (5.5%)

a. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile

3rd Dose Vaccine Administration Timing Mostly Occurred 8-9 months after Dose 2: 5 to <12 Years of Age Safety population

		BNT162b2 (10µg) N=401 n (%)
Vaccinated Dose 3		**401 (100.0)**
Dose 3 (Time from Dose 2)	**≥5 to <6 Months**	**1 (0.2)**
	≥6 to <7 Months	**1 (0.2)**
	≥7 to <8 Months	**51 (12.7)**
	≥8 to <9 Months	**348 (86.8)**

Data cutoff date 22Mar2022

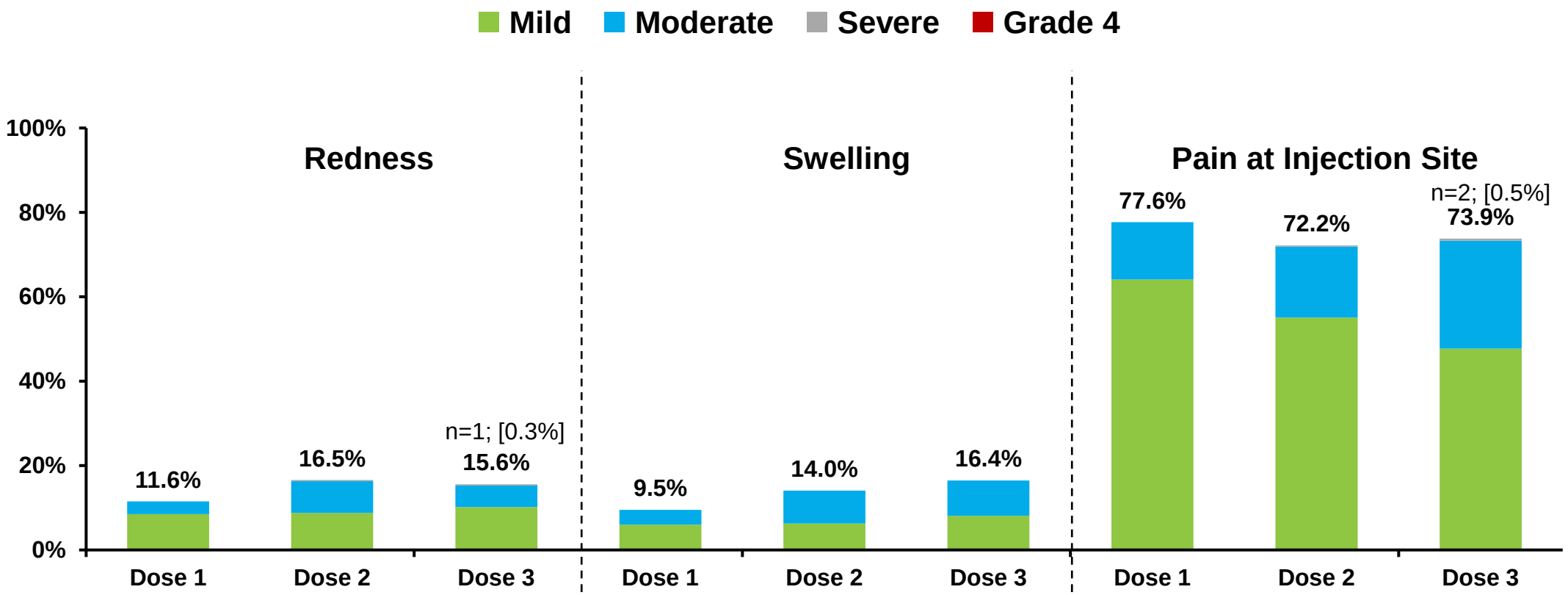
Dose 3 Mean Follow-up Time of 1.3 Months
5 to <12 Years of Age Safety population (Unblinded)

		BNT162b2 (10µg) N=401 n (%)
Time from Dose 3 to cutoff date	<1 Month	0
	≥1 to <2 Months	401 (100.0)
	Mean	1.3 (0.17)
	Median	1.3
	Min, Max	(1.0, 1.8)

Data cutoff date 22Mar2022

Safety

Local Reactions 7 Days After Each Dose Mostly Mild to Moderate

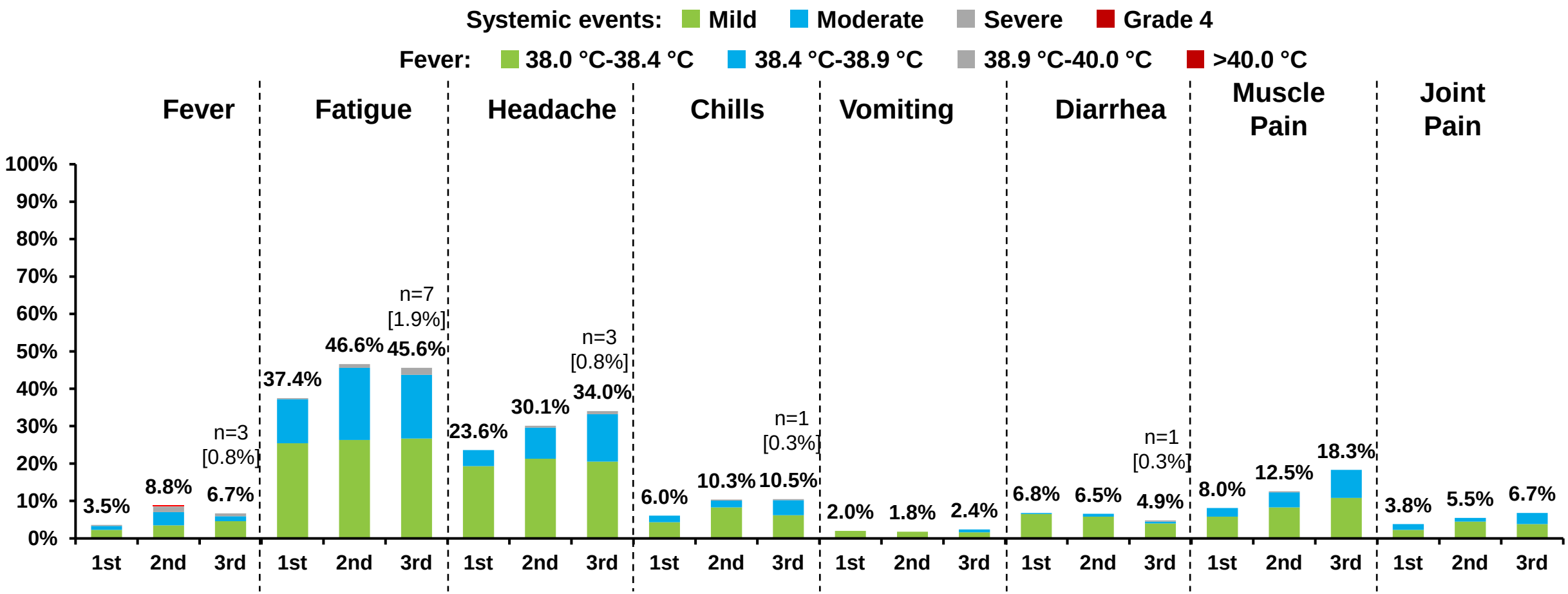


Redness and swelling severity definition: Mild: ≥0.5 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 cm Grade 4= necrosis
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Dose 1: N=398; Dose 2: N=399; Dose 3: N=371

Severe reactions at Dose 3:

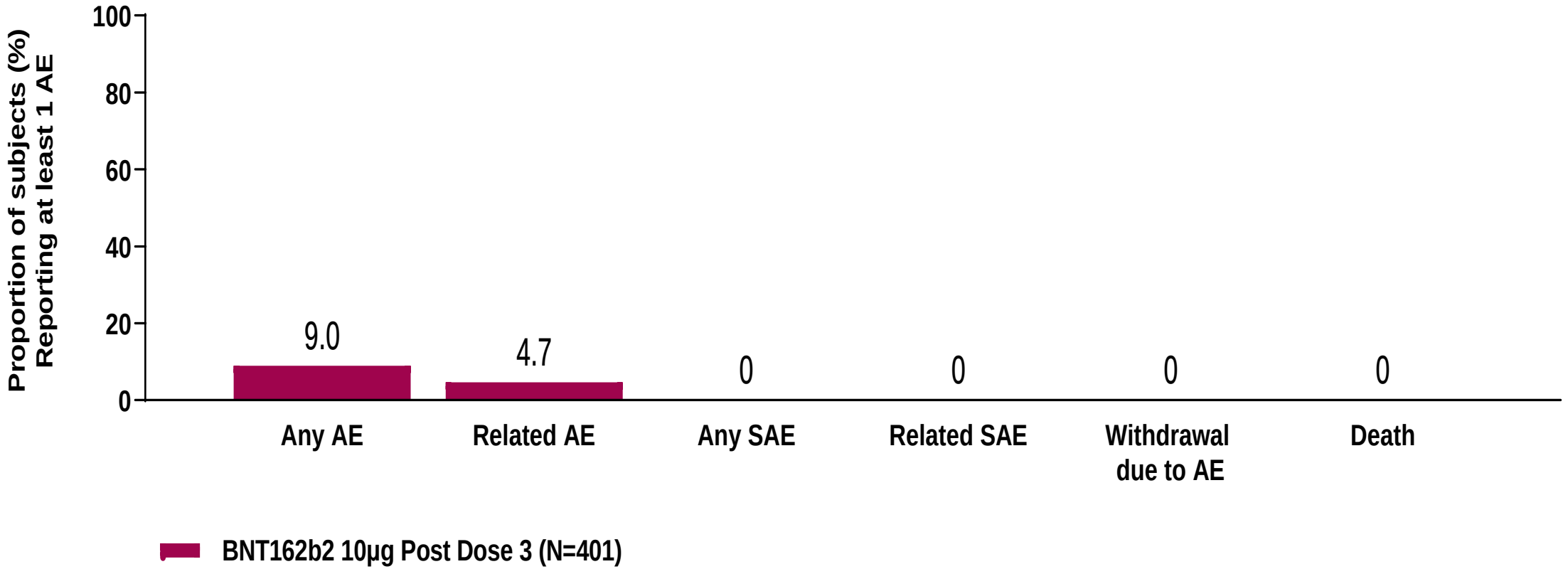
- Pain at the injection site: 2 participants – onset within 1-2 days of vax resolved with 2 days of which 1 participant also reported severe headache – no other symptoms.
- Redness – 1 participant with moderate redness Day 2 and became severe on Day 4. Duration 12 days.

Systemic Events Within 7 Days After Each Dose Mostly Mild to Moderate

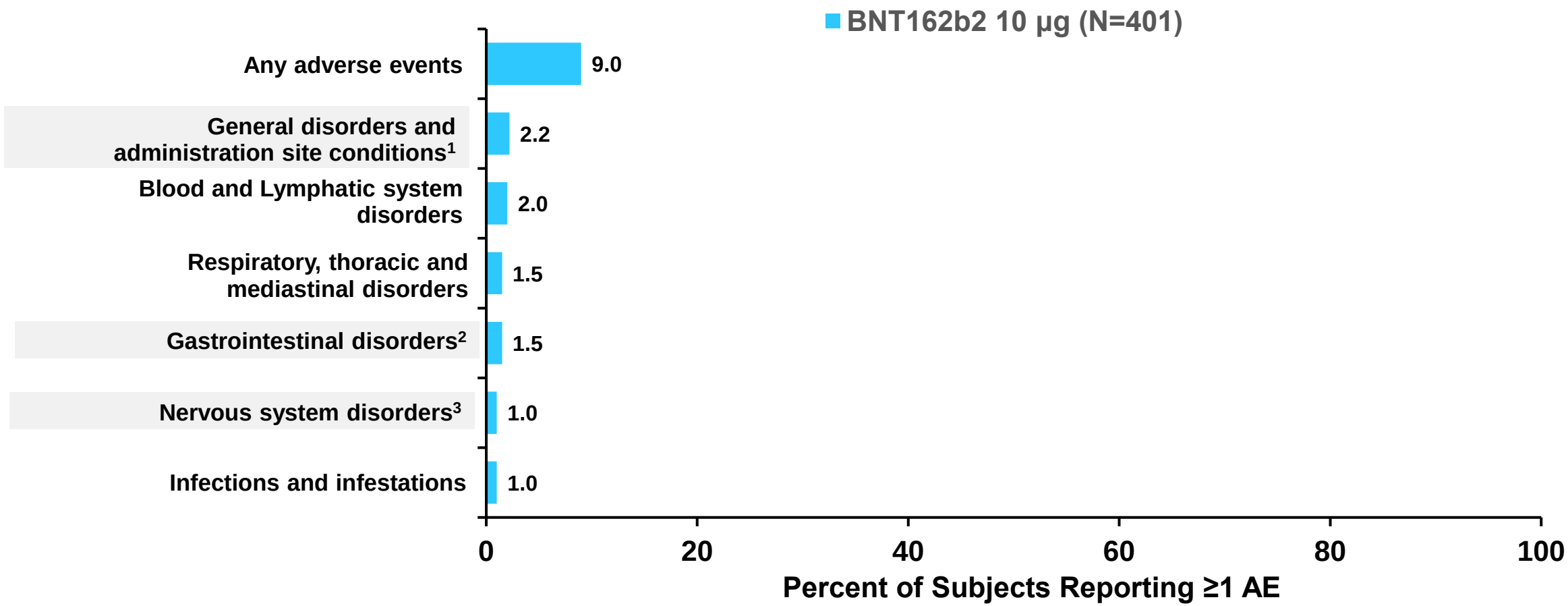


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
Dose 1: N=398; Dose 2: N=399; Dose 3: N=371

Overall Dose 3 to Cut-off (22Mar2022) Adverse Events Were Consistent with the 2 Dose Series 5 to <12 year olds



Adverse Events (≥1.0%) Consistent with Reactogenicity Events and other Events Typical for This Age Group: System Organ Class for 5 to <12 year olds From Dose 3 to 1 Month After Dose 3 - Safety Population



1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue
2. Predominantly reflects systemic events of diarrhoea and vomiting
3. Predominantly reflects systemic events of headache

Adverse Events of Clinical Interest and other important terms

Few AEs of clinical interest corresponding to those requested by FDA or CDC list of AESIs

- None of the following were reported in BNT162b2 recipients up to the data cutoff point:
  - Anaphylaxis
  - Myocarditis/pericarditis
  - Bell’s palsy (or facial paralysis/paresis)
  - Appendicitis

- Rash - 1 event
  - Mild facial rash
  - Considered unrelated to vaccine by the investigator → wearing a face mask
  - Onset was 11 days post dose 3 and resolved 4 days later

Lymphadenopathy observed in 5 to <12 year old age group, but Lower Frequency Compared to Adults with 3rd Dose of BNT162b2 30 ug

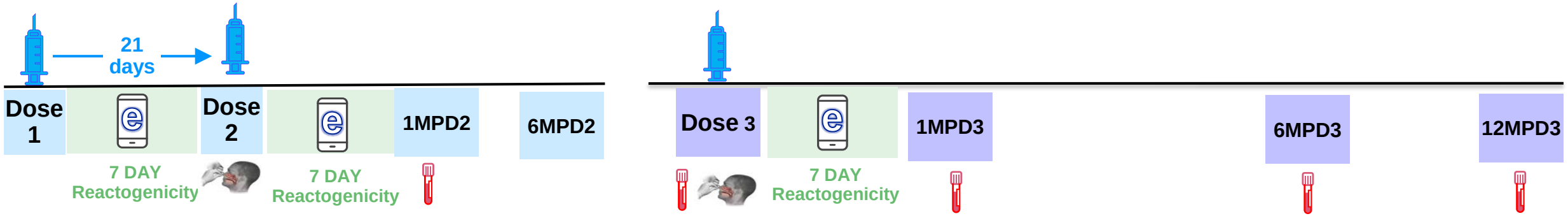
- Post Dose 3, 10 (2.4%) BNT162b2 participants
  - Post Dose 2 → 0.9%
  - Post Dose 3 adults (30µg) → 5.2%
- Overall, mild and considered to be related by investigator
- Occurred primarily in axillary or cervical nodes
- Onset within 2 days of booster vaccination
- Reported as resolved within ~1 week after onset

Overall Safety Conclusions

- Safety data from 401 subjects who received a booster (3rd) dose of BNT162b2 10 µg did not identify any new safety concerns
- Reactogenicity was mostly mild to moderate and short lived after third dose and generally comparable to that observed after the second dose
- AESIs were limited to one case of rash

Immunogenicity

Descriptive Immunogenicity Analysis: 1MPD3 compared to 1MPD2 5 to <12 Years of Age



3-Dose Immunogenicity Set

- 123 participants completed 1MPD3 by 15 Mar 2022 who with/without evidence of infection.
  - 30: part of 1MPD2 immuno-bridging subset.
- Evaluable Without evidence of infection
  - Of 123 → 67
  - Of 30 → 29 (contributed to the Omicron analysis)

2-Dose Set

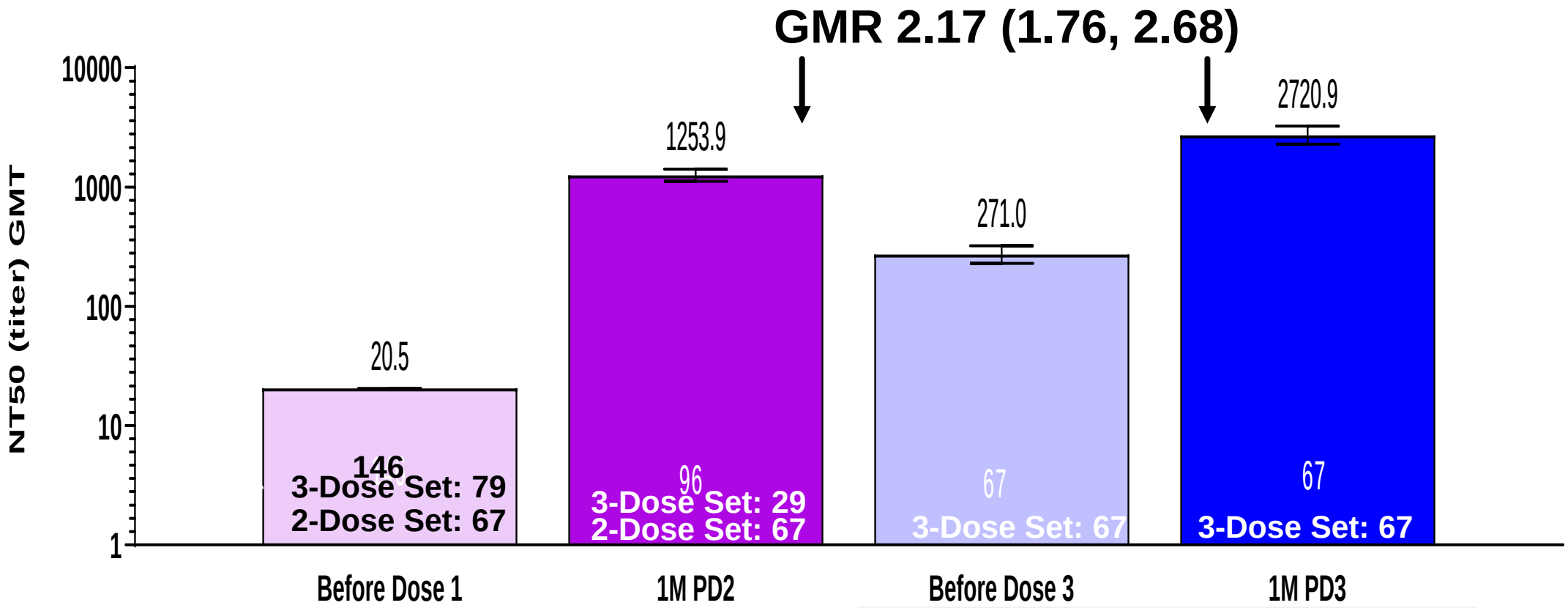
Additional 67 without evidence of infection randomly selected 1MPD2 evaluable population

Dose 2 and Dose 3 evaluable sets -- Received all doses of vaccine at the same dose level as randomized (ie, two or three doses) and did not have important deviations to study procedure

COVID Illness Visits continue

BNT162b2 10 µg 2-Dose and 3-Dose Sets elicited robust neutralization titers against SARS-CoV-2 wild type in participants without evidence of prior infection: 5 to <12 Years of Age – Evaluable Immunogenicity Population

GMT and GMRs were similar to participants with and without prior evidence of infection



1MPD3/Dose 3 GMFR
Without evidence of infection → 10.0
With and without evidence of infection → 6.2

NT50, 50% neutralizing titer; Wild type, USA-WA-1/2020

High Seroresponse Rate (98.5%) against SARS-CoV-2 wild type After Dose 3 in participants without evidence of prior infection: 5 to <12 Years of Age – Evaluable Immunogenicity Population

Assay	Dosing/ Sampling Time Point	BNT162b2 (10µg)								
		3 Dose Set			2 Dose Set			Total		
		N	n	% (95% CI)	N	n	% (95% CI)	N	n	% (95% CI)
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	29	29	100 (88.1, 100.0)	67	67	100.0 (94.6, 100.0)	96	96	100.0 (94.6, 100.0)
	3/Prevax	67	52	77.6 (65.8, 86.9)				67	52	77.6 (65.8, 86.9)
	3/1 Month	67	66	98.5 (92.0, 100.0)				67	66	98.5 (92.0, 100.0)

- 3-Dose immunogenicity set included the first 123 participants received Dose 3 and completed 1 month post–Dose 3 visit prior to March 15, 2022. Among those, 30 had blood sample collection at 1 month post–Dose 2.
- 2-Dose immunogenicity set included extra 67 participants randomly selected from previous Dose-2 evaluable immunogenicity population and without evidence of infection up to 1-month post–Dose 2 subset used for 2-dose immunobridging analysis
- Seroresponse defined as a ≥4 fold rise from baseline. If baseline < LLOQ, then postvaccination result ≥4 x LLOX is considered a seroresponse

Booster (3rd) dose of BNT162b2 10 µg Elicited Neutralizing Titers Against a SARS-CoV-2 Omicron in Participants Without Evidence of Prior Infection

5 to <12 Years of Age – Evaluable Immunogenicity Population

		BNT162b2 (10µg)		
Assay	Dosing/ Sampling Time Point	N	GMT (95% CI)	GMR
SARS-CoV-2 FFRNT strain B.1.1.529 (Omicron) - NT50 (titer)	2/1 Month	29	27.6 (22.1, 34.5)	22
	3/1 Month	17	614.4 (410.7, 919.2)	
SARS-CoV-2 FFRNT reference strain - NT50 (titer)	2/1 Month	29	323.8 (267.5, 392.1)	5
	3/1 Month	17	1702.8 (1282.6, 2260.7)	

FFRNT = Fluorescent focus reduction neutralization test

Booster (3rd) dose of BNT162b2 10 µg Elicited Neutralizing Titers Against a SARS-CoV-2 Omicron in Participants With and Without Evidence of Prior Infection

5 to <12 Years of Age – Evaluable Immunogenicity Population

		BNT162b2 (10µg)		
Assay	Dosing/ Sampling Time Point	N	GMT (95% CI)	GMR
SARS-CoV-2 FFRNT strain B.1.1.529 (Omicron) - NT50 (titer)	2/1 Month	30	27.3 (22.0, 33.9)	36
	3/1 Month	30	992.7 (675.9, 1458.1)	
SARS-CoV-2 FFRNT reference strain - NT50 (titer)	2/1 Month	30	335.1 (275.1, 408.3)	6
	3/1 Month	30	2152.7 (1714.9, 2702.2)	

FFRNT = Fluorescent focus reduction neutralization test

Immunogenicity Conclusions

- In participants with and without evidence of prior infection, administration of a booster (3rd) dose of BNT162b2 10 µg elicited robust neutralization titers against SARS-CoV-2 wild type
- A booster (3rd) dose of BNT162b2 10µg elicited neutralizing titers against SARS-CoV-2 Omicron in participants with and without evidence of prior infection
- Overall the immune response associated with a booster (3rd) dose of BNT162b2 10µg given at least 6 months after the second dose is expected to confer protection against COVID-19, including that due to Omicron

Questions