Vaccines and Related Biological Products Advisory Committee Meeting

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BNT162b2 (COVID-19 Vaccine, mRNA) Request for Emergency Use Authorization in Individuals 6 Months Through 4 Years of Age

Vaccines and Related Biological Products Advisory Committee

June 15, 2022

William C. Gruber, MD, FAAP, FIDSA, FPIDS

Senior Vice President
Vaccine Clinical Research
and Development
Pfizer Inc

June 15, 2022

Presentation Agenda

1	**Introduction**	
2	**Unmet Medical Need**	
3	**Phase 2/3 Clinical Data**	• Safety • Immunogenicity • Efficacy
4	**Benefit Risk**	

Unmet Medical Need in Children 6 Months to <5 Years of Age

- **Severe COVID-19 occurs in children <5 years of age**
  - As of May 2022, 45,000 hospitalizations[1] (24% require ICU)[1,2] and 475 deaths[3]
  - Roughly 50% of these hospitalizations were likely due to Omicron[4]
  - Burden comparable to influenza – for which children are routinely immunized[5]
- **Severe COVID-19 outcomes are unpredictable and can occur in healthy children**
  - 64% of hospitalizations in children <5 years occur in those without comorbidities[2]
- **COVID-19 can cause additional long-term sequelae in children**
  - 3–6% of children report continued symptoms for >12 weeks[6]
- **Pandemic adversely impacts developmental and psychosocial well-being[7]**

1. Hospitalizations through May 14, 2022. CDC COVID Data Tracker. COVID-NET Laboratory-confirmed COVID-19 hospitalizations. Available from: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network. May 20, 2022; Counts computed from rates and population size.
2. Marks KJ, Whitaker M, Agathis NT, et al. Hospitalization of Infants and Children Aged 0–4 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 2020–February 2022. MMWR 2022; 71:429-436. doi: http://dx.doi.org/10.15585/mmwr.mm7111e2
3. Deaths through May 19, 2022. CDC COVID Data Tracker. Demographic Trends of COVID-19 cases and deaths in the US reported to CDC. Available from: https://covid.cdc.gov/covid-data-tracker/#demographics
4. Computed by multiplying weekly hospitalization counts from CDC COVID Data Tracker by the biweekly proportion of specimens testing positive for Omicron from CoVariants.org
5. Delahoy MJ, Ujamaa D, Taylor CA, et al. Comparison of Influenza and COVID-19-Associated Hospitalizations among Children < 18 Years Old in the United States-FluSurv-NET (October-April 2017-2021) and COVID-NET (October 2020-September 2021). Clin Infect Dis 2022; May 20:ciac388. doi: 10.1093/cid/ciac388.
6. Office for National Statistics United Kingdom. Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK: 6 May 2022, Table 2 [updated May 6, 2022]. Available from: https://www.ons.gov.uk/file?uri=%2fpeoplepopulationandcommunity%2fhealthandsocialcare%2fconditionsanddiseases%2fdatasets%2falldatarelatingtoprevalenceofongoingsymptomsfollowingcoronaviruscovid19infectionintheuk%2f6may2022/ongoingsymptomsfollowingcovid1920220506accessible.xlsx.
7. Centers for Disease Control and Prevention. COVID-19 Parental Resources Kit – Early Childhood [updated February 28, 2022]. Available from: https://www.cdc.gov/mentalhealth/stress-coping/parental-resources/early-childhood/index.html

The Need for 3 mRNA Vaccine Doses Against Omicron

- **Omicron is significantly more transmissible than prior variants[1]**
- **In adult populations, 2 doses of current mRNA COVID-19 vaccines do not adequately neutralize Omicron[2-5]**
- **A 3rd dose increases breadth of coverage and can neutralize Omicron[3-5]**
- **Real-world data show that a 3rd dose significantly improves protection against Omicron-related symptomatic disease[6-10] and severe illness[8-11]**
- **Given this emerging evidence indicating that 3 doses of mRNA vaccine are needed against Omicron – we studied 3 doses of BNT162b2 in children 6 months through <5 years of age**

1. Centers for Disease Control and Prevention. (2022, March 29) Omicron Variant: What You Need to Know. https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html
2. Cele S, Jackson L, Khoury DS, et al. Omicron Extensively but Incompletely Escapes Pfizer BNT162b2 Neutralization. Nature 2022; 602(7898):654-656. doi: 10.1038/s41586-021-04387-1.
3. Schmidt F, Muecksch F, Weisblum Y, et al. Plasma Neutralization of the SARS-CoV-2 Omicron Variant. N Engl J Med 2022; 386(6):599-601. doi: 10.1056/NEJMc2119641.
4. Nemet I, Kliker L, Lustig Y, et al. Third BNT162b2 Vaccination Neutralization of SARS-CoV-2 Omicron Infection. N Engl J Med 2022; 386(5):492-494. doi: 10.1056/NEJMc2119358.
5. Pfizer Inc. (2021, December 08) Pfizer and BioNTech Provide Update on Omicron Variant [Press release]. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant
6. Fleming-Dutra KE, Britton A, Shang N, et al. Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance. JAMA 2022; May 13:e227493. doi: 10.1001/jama.2022.7493.
7. Klein NP, Stockwell MS, Demarco M, et al. Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Nonimmunocompromised Children and Adolescents Aged 5-17 Years - VISION Network, 10 States, April 2021-January 2022. MMWR 2022;71(9):352-358. doi: 10.15585/mmwr.mm7109e3.
8. Ferdinands JM, Rao S, Dixon BE, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. MMWR 2022; 71(7):255-63. doi: http://dx.doi.org/10.15585/mmwr.mm7107e2.
9. Thompson MG, Natarajan K, Irving SA, et al. Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. MMWR 2022; 21;71(4):139-45. doi: http://dx.doi.org/10.15585/mmwr.mm7104e3.
10. Tartof SY, Slezak JM, Puzniak L, et al. Immunocompromise and Durability of BNT162b2 Vaccine Against Severe Outcomes due to Omicron and Delta Variants. Lancet Respir Med 2022; S2213-2600(22)00170-9. doi: 10.1016/S2213-2600(22)00170-9.
11. Lauring AS, Tenforde MW, Chappell JD, et al. Clinical Severity of, and Effectiveness of mRNA Vaccines Against, Covid-19 from Omicron, Delta, and Alpha SARS-CoV-2 Variants in the United States: Prospective Observational Study. BMJ 2022; 376:e069761. doi: 10.1136/bmj-2021-069761.

Pfizer/BioNTech Seeking Emergency Use Authorization of 3 µg Dose of BNT162b2 in Children 6 Months Through 4 Years of Age

3 µg
dose level selected
(Maroon cap and label)

Proposed Indication and Schedule

- Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months through 4 years of age
- Administered intramuscularly as a **3 dose vaccine (0.2 mL each)**
- 2 doses 3 weeks apart followed by a third dose at least 8 weeks after the second dose

Clinical Data

Pfizer-BioNTech COVID-19 Vaccine BNT162b2 for Pediatric Populations: 6 Months to <5 Years - Study Overview

Phase 1

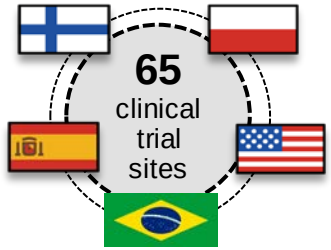
64
PARTICIPANTS

6 months through 4 years

Identification of preferred dose level

- **3 µg**
- **10 µg**

Phase 2/3



2:1
randomization

- **N=3,013 BNT162b2**
- **N=1,513 Placebo (Saline)**

Non-inferior immune responses have been established to infer vaccine efficacy

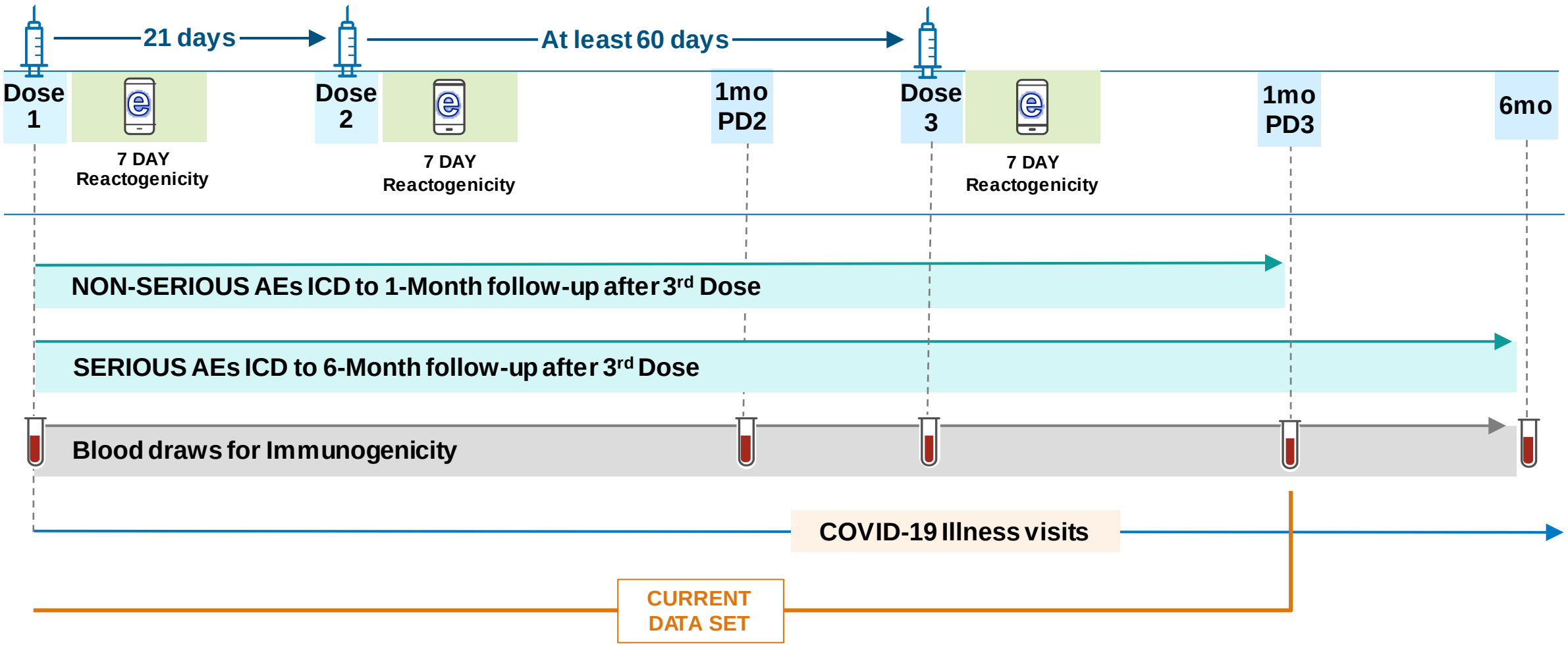
Children
6 months to <5-year-olds

COMPARED TO

16–25-year-olds
from the pivotal Phase 3 study

Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy

Phase 2/3 Timelines of Participants



Safety

Data Cut-off date: 29 April 2022

AGE
2 to <5

Demographics Were Balanced between Vaccine and Placebo Recipients

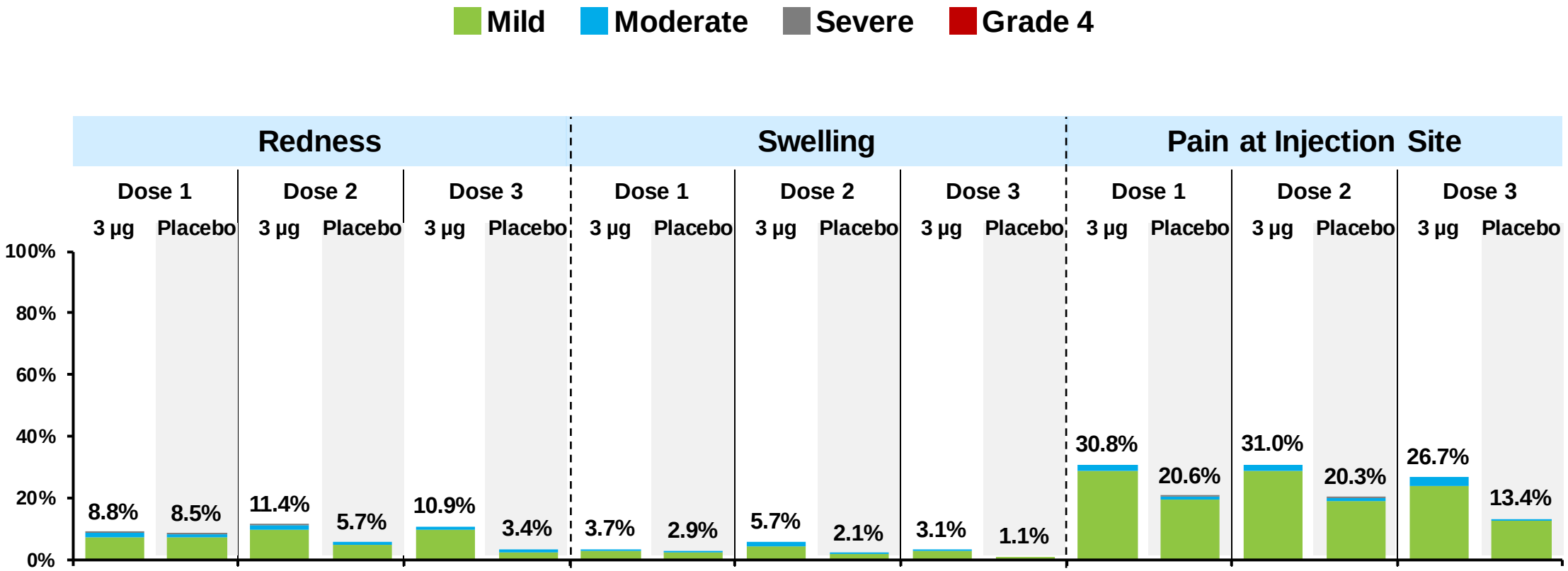
Phase 2/3 Safety Population (N=2750)

		BNT162b2 (3 µg) N=1835	Placebo N=915
Sex, n (%)	Male	901 (49.1)	471 (51.5)
	Female	934 (50.9)	444 (48.5)
Race, n (%)	White	1469 (80.1)	720 (78.7)
	Black or African American	94 (5.1)	41 (4.5)
	American Indian or Alaska native	<1%	<1%
	Asian	127 (6.9)	76 (8.3)
	Native Hawaiian or other Pacific Islander	<1%	<1%
	Multiracial	131 (7.1)	69 (7.5)
	Not reported	9 (0.5)	4 (0.4)
Ethnicity, n (%)	Hispanic/Latino	264 (14.4)	120 (13.1)
	Non-Hispanic/non-Latino	1568 (85.4)	795 (86.9)
	Not reported	<1%	0
Obese[a], n (%)	Yes	120 (6.5)	45 (4.9)
Baseline SARS-CoV-2 positive[b]	Yes	233 (12.7)	125 (13.7)
Comorbidities[c], n (%)	Yes	222 (12.1)	130 (14.2)

a. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.
b. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
c. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile)

AGE
2 to <5

No Increase in Local Reactions from Dose 2 to 3 Mostly Mild to Moderate with No Grade 4 Events

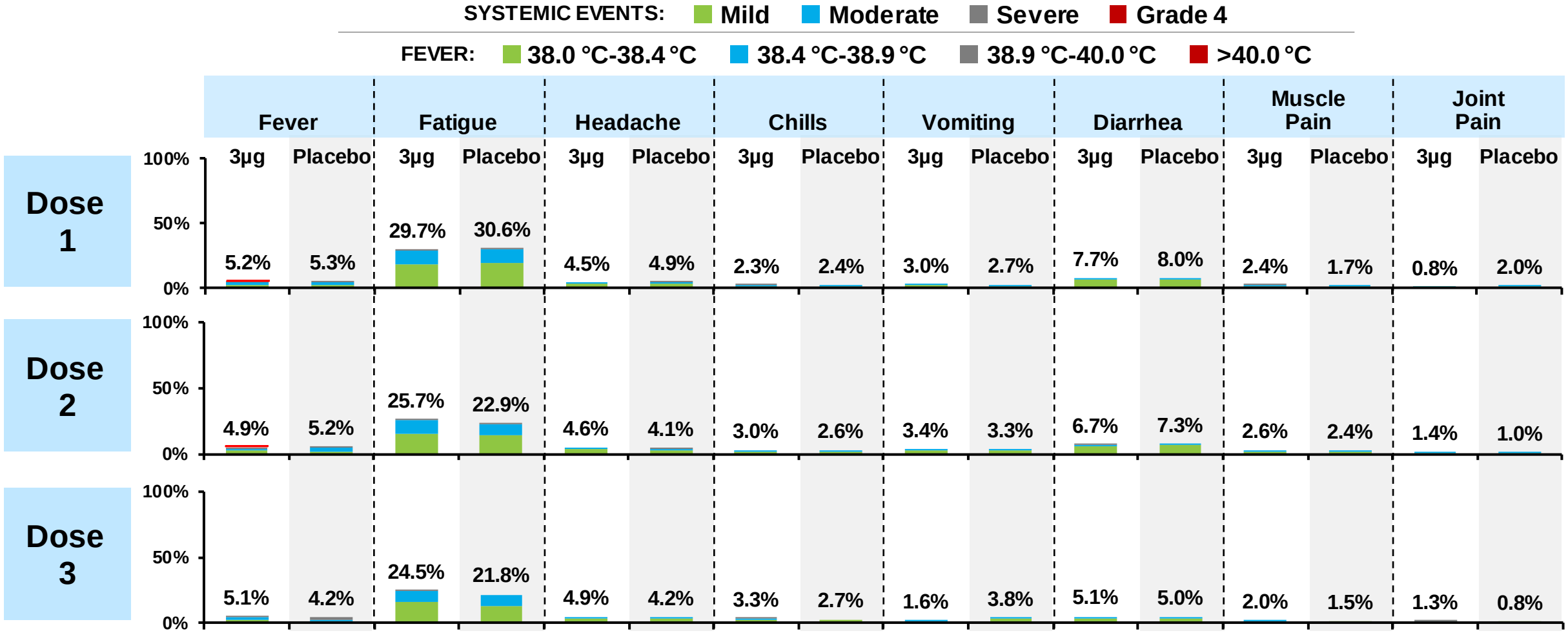


Redness and swelling severity definition: Mild= ≥0.5-2cm, Moderate= >2-7 cm; Severe= >7cm; Grade 4= necrosis (or exfoliative dermatitis for redness only)
Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Dose 1: N=2734 Dose 2: N=2657 Dose 3: N=814

AGE
2 to <5

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

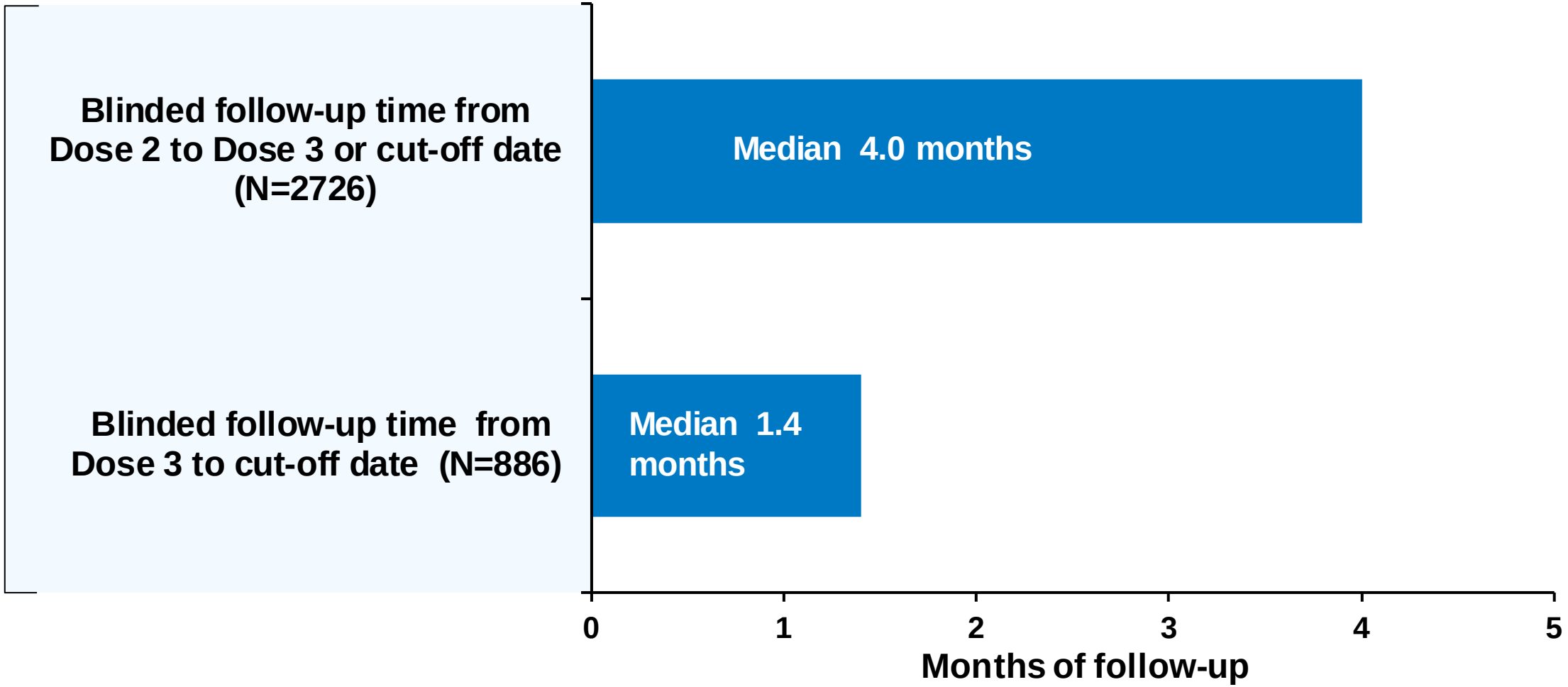
Similar incidence seen between BNT162b2 and placebo



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=2734 Dose 2: N=2657; Dose 3: N=814

AGE
2 to <5

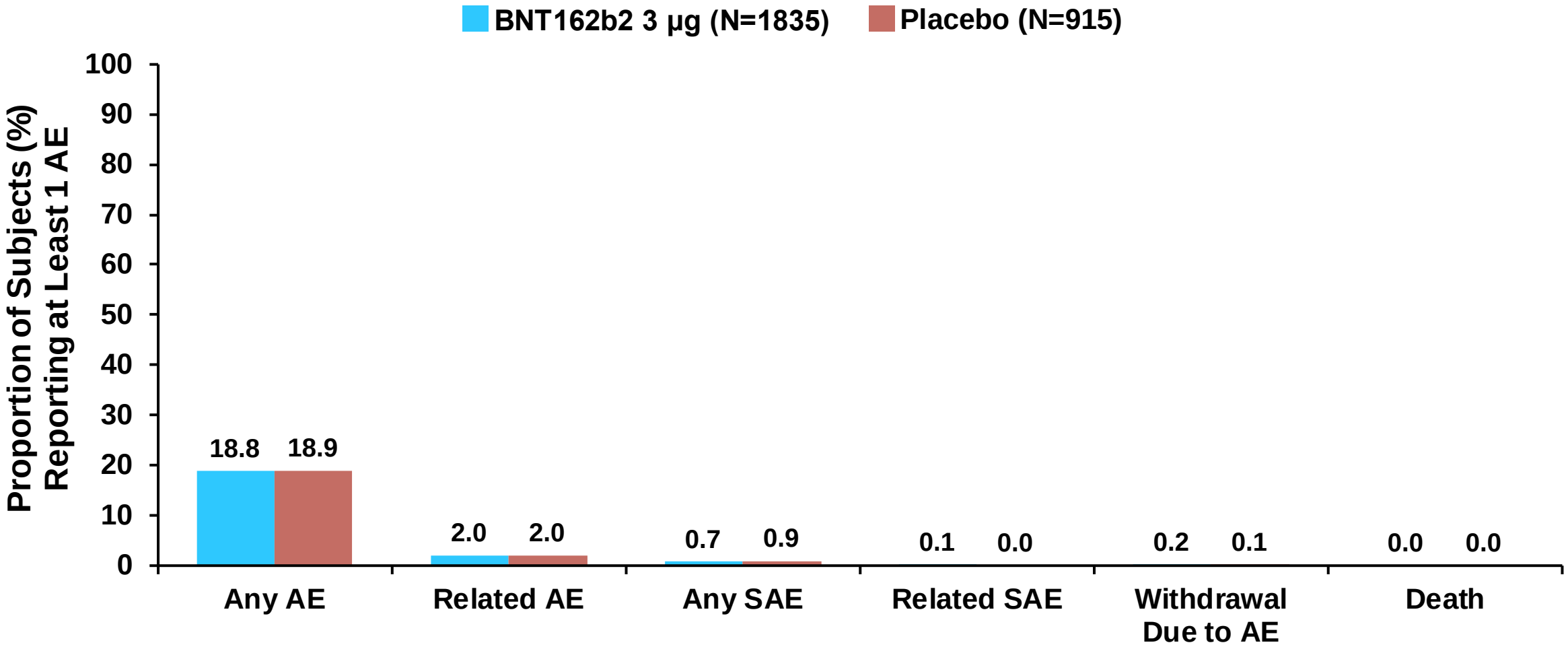
Safety Follow-up



AGE
2 to <5

Adverse Events: Similar Incidence Seen Between BNT162b2 and Placebo

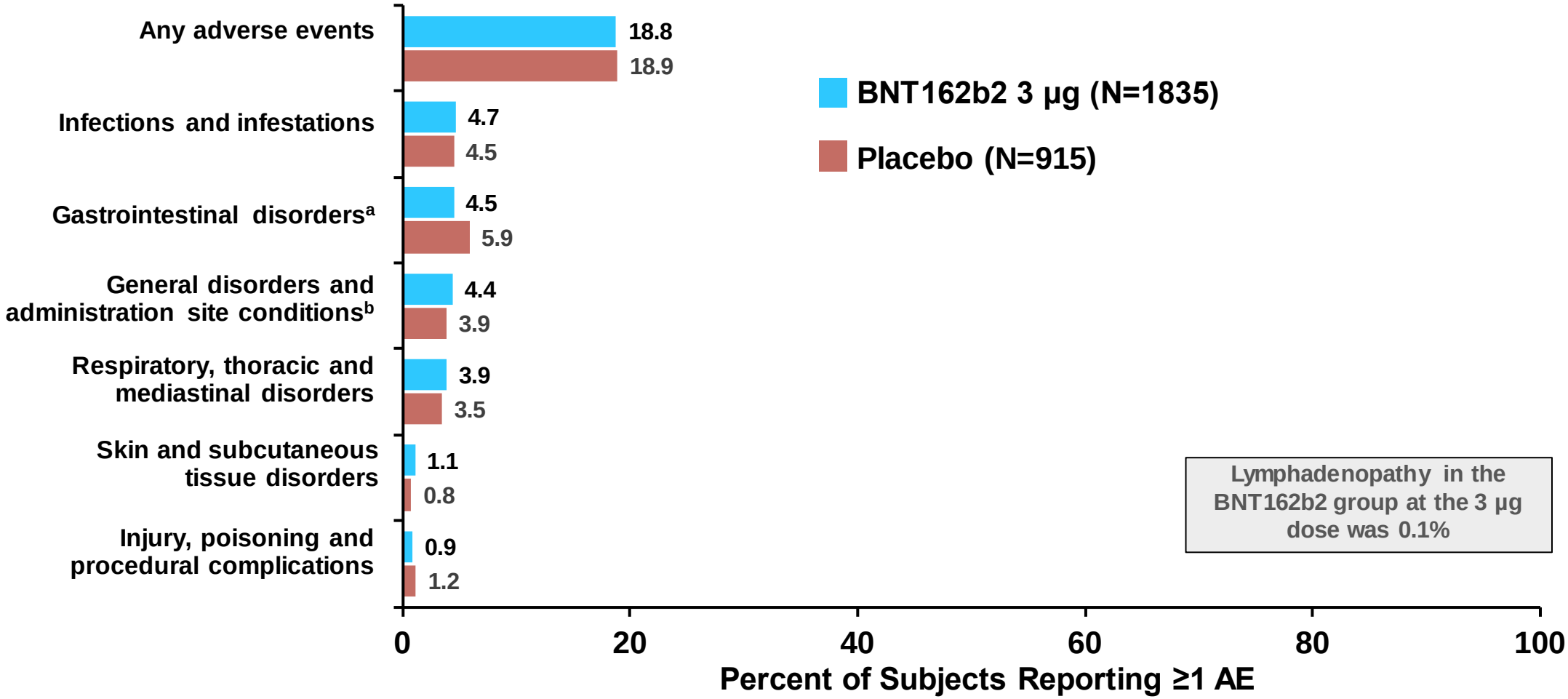
Dose 1 to Data Cut-off (29 April 22)



AGE
2 to <5

Adverse Events ≥1.0% by System Organ Class Were Comparable between Vaccine and Placebo Recipients

Dose 1 to Data Cut-off (29 April 22) | Safety Population



a. Predominantly reflect vomiting and diarrhea.
b. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue.

AGE
6 mo. to <2

Demographics Were Balanced between Vaccine and Placebo Recipients

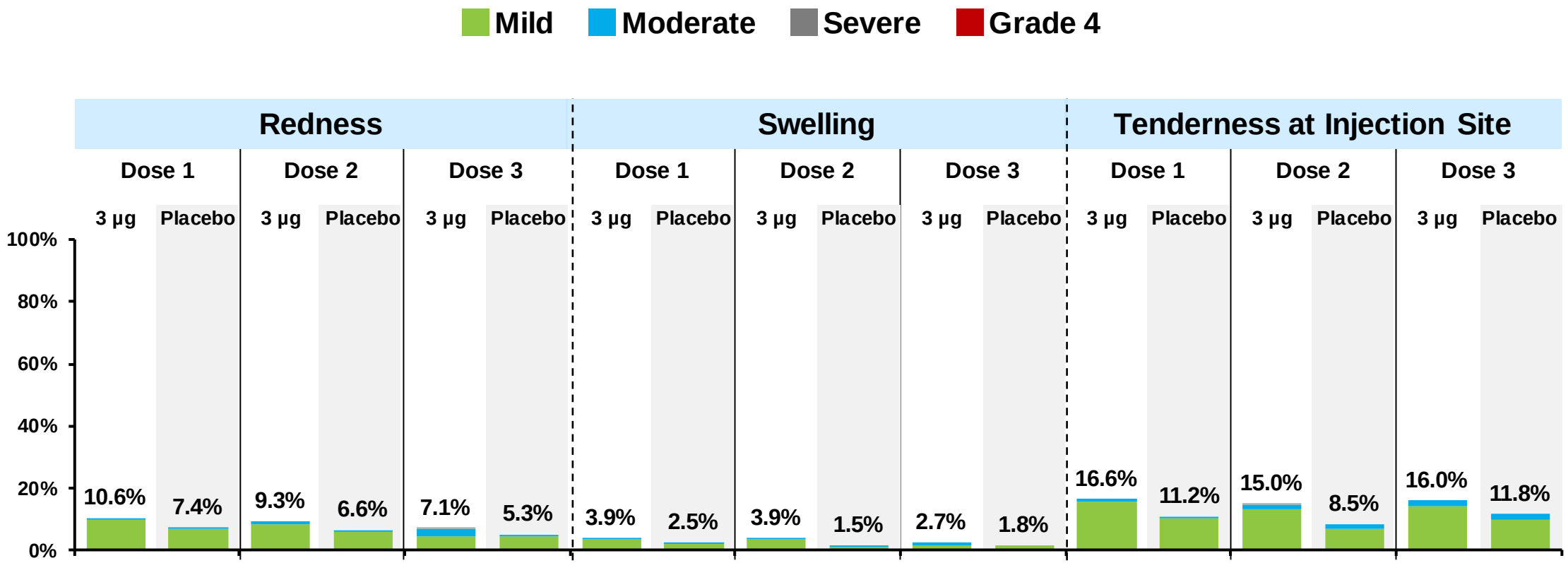
Phase 2/3 Safety Population (N=1776)

		BNT162b2 (3 µg) N=1178	Placebo N=598
Sex, n (%)	Male	589 (50.0)	291 (48.7)
	Female	589 (50.0)	307 (51.3)
Race, n (%)	White	922 (78.3)	480 (80.3)
	Black or African American	42 (3.6)	24 (4.0)
	American Indian or Alaska native	<1%	<1%
	Asian	91 (7.7)	40 (6.7)
	Multiracial	117 (9.9)	49 (8.2)
	Not reported	3 (0.3)	4 (0.7)
Ethnicity, n (%)	Hispanic/Latino	161 (13.7)	64 (10.7)
	Non-Hispanic/non-Latino	1014 (86.1)	530 (88.6)
	Not reported	<1%	<1%
Baseline SARS-CoV-2 positive[a]	Yes	89 (7.6)	44 (7.4)
Comorbidities[b], n (%)	Yes	50 (4.2)	34 (5.7)

a. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
b. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088

AGE
6 mo. to <2

Local Reactions were Mostly Mild to Moderate with No Grade 4 Events

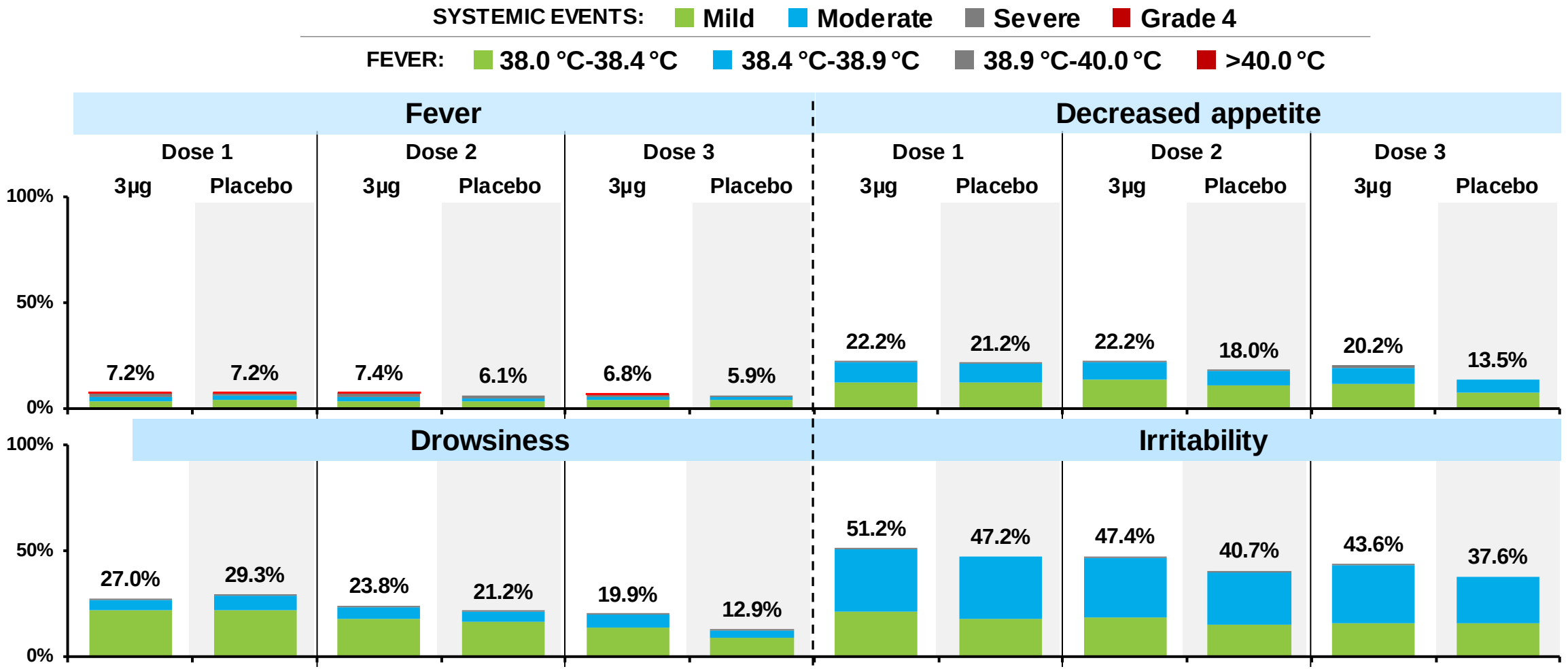


Redness and swelling severity definition: Mild= ≥0.5-2cm, Moderate= >2-7 cm; Severe= >7cm; Grade 4= necrosis (or exfoliative dermatitis for redness only)
Tenderness at injection site severity definition: Mild=hurts with gentle touch; Moderate=crying with gentle touch; Severe=limitation of limb movement; Grade 4=ER visit or hospitalization
Dose 1: N=1768; Dose 2: N=1738; Dose 3: N=535

AGE
6 mo. to <2

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

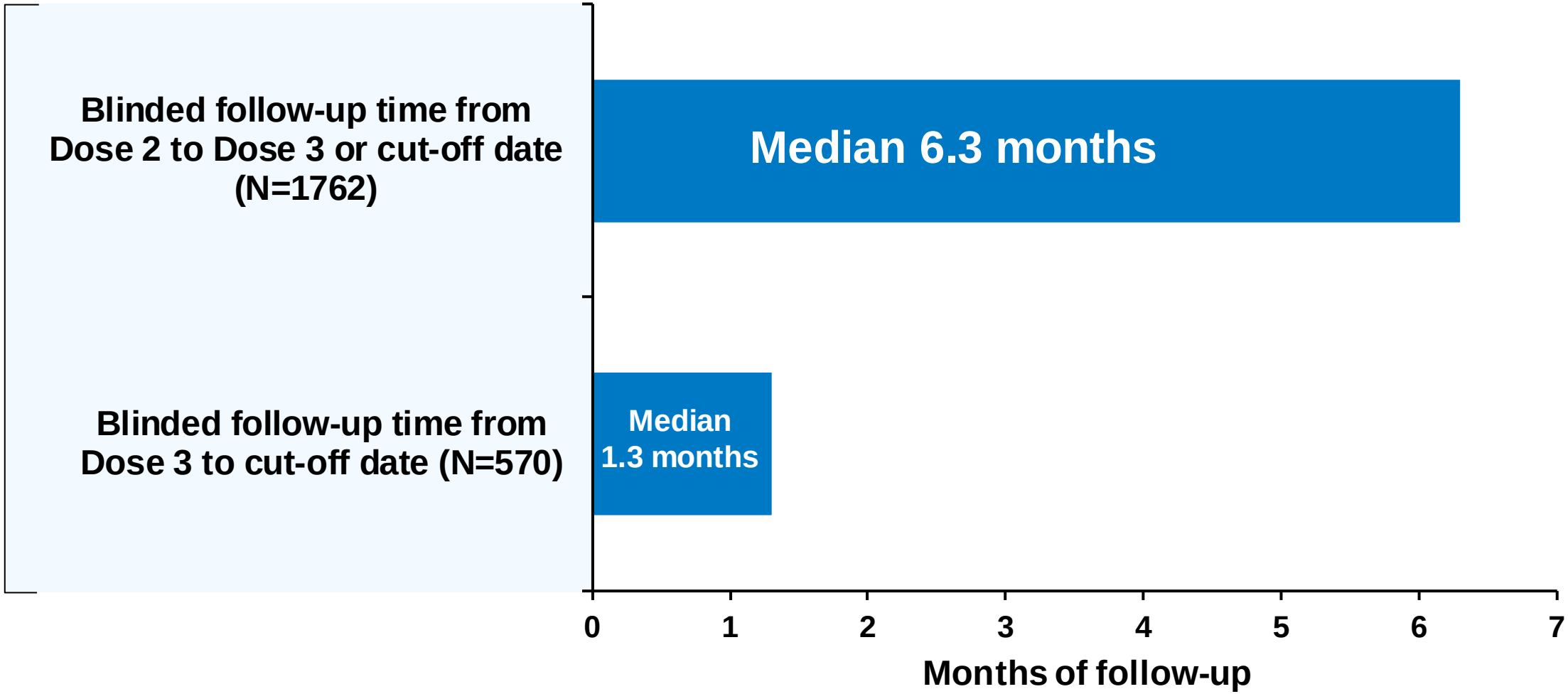
Similar incidence seen between BNT162b2 and placebo



Decreased appetite severity definition: Mild=decreased interest in eating; Moderate=decreased oral intake; Severe=refusal to feed; Grade 4=ER visit or hospitalization
Drowsiness severity definition: Mild=increased/prolonged sleeping; Moderate: slightly subdued; Severe=Disabling/not interested in daily activity; Grade 4=ER visit or hospitalization
Irritability severity definition: Mild=easily consolable; Moderate=requires increased attention; Severe=inconsolable; Grade 4=ER visit or hospitalization
Dose 1: N= 1768; Dose 2: N= 1738; Dose 3: N=535

AGE
6 mo. to <2

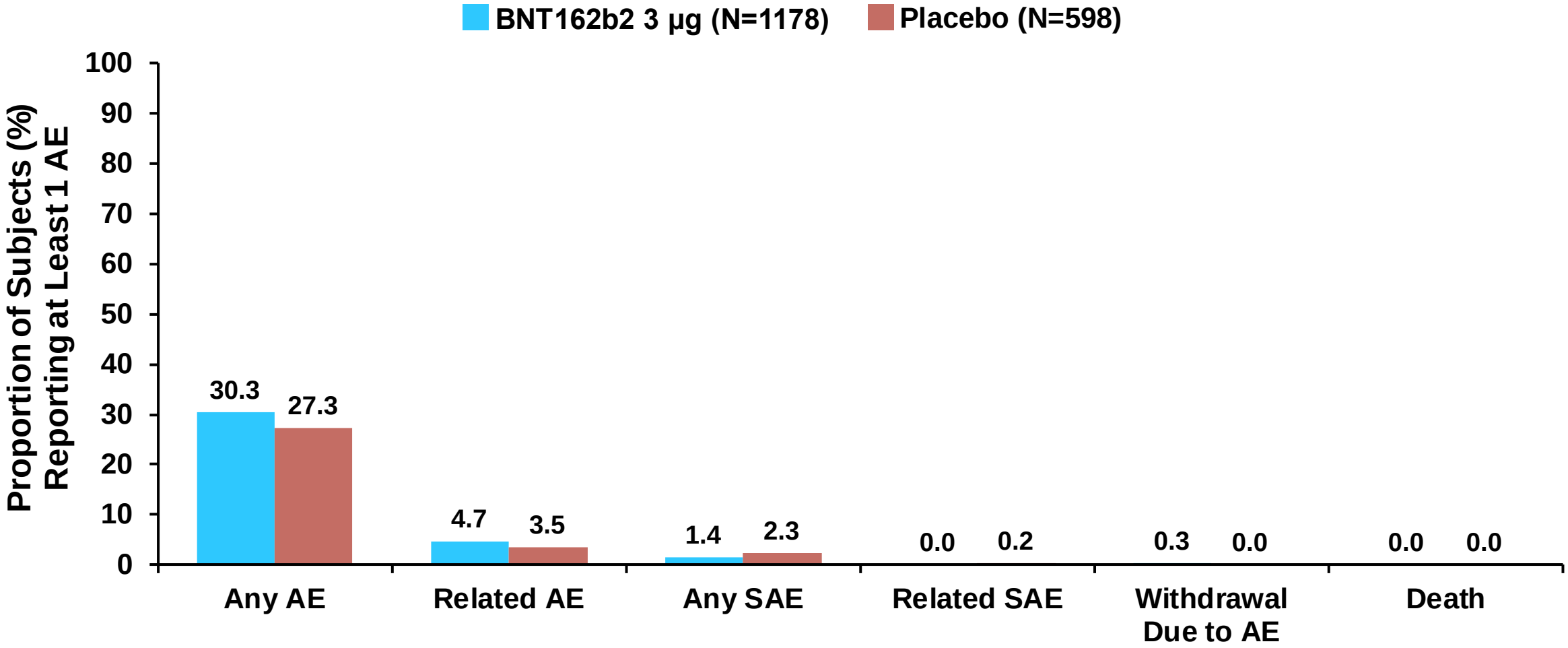
Safety Follow-up



AGE
6 mo. to <2

Adverse Events: Similar Incidence Between BNT162b2 and Placebo with No Meaningful Difference Noted

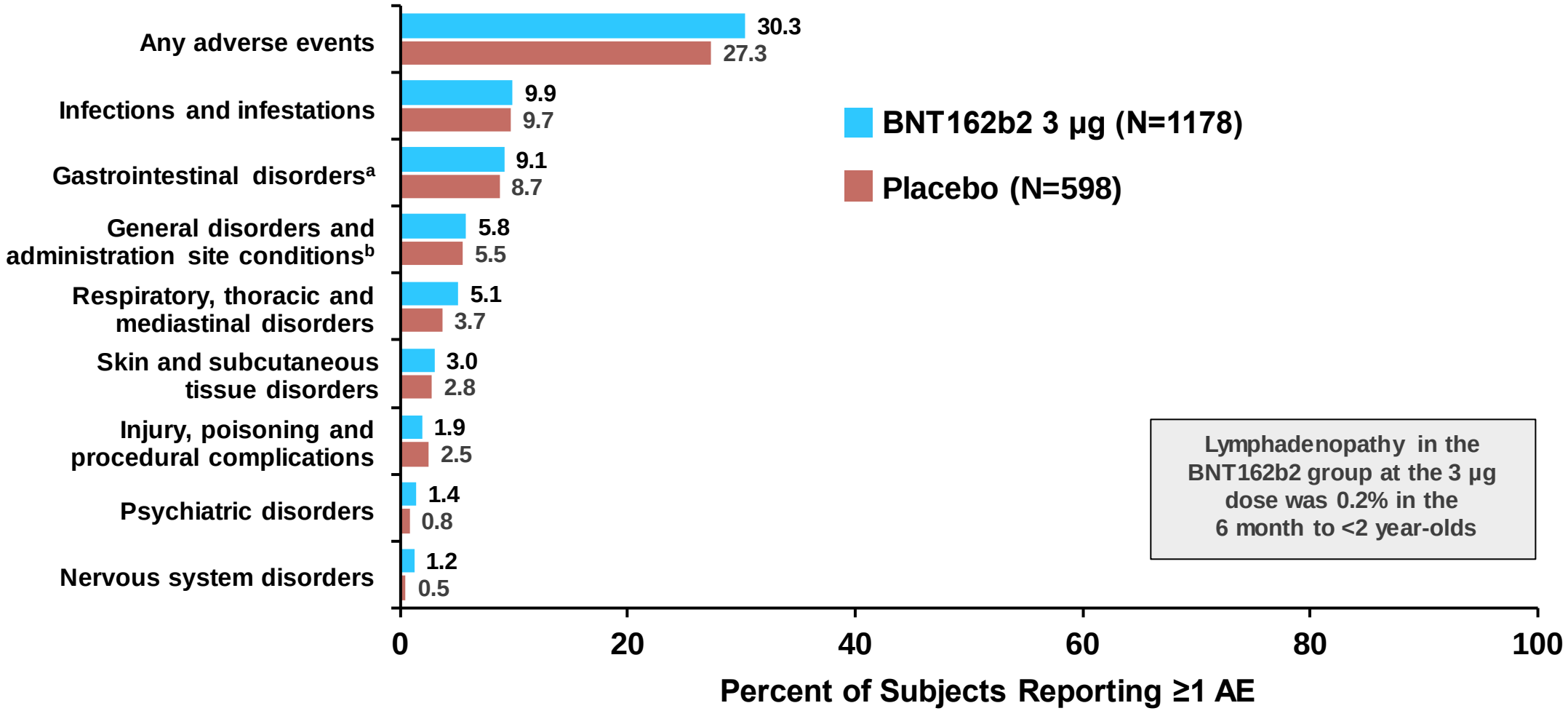
Dose 1 to Data Cut-off (29 April 22)



AGE
6 mo. to <2

Adverse Events ≥1.0% by System Organ Class Were Comparable between Vaccine and Placebo Recipients

Dose 1 to Data Cut-off (29 April 22) | Safety Population



a. Predominantly reflect vomiting and diarrhea
b. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue

AGE
6 mo. to <5

Few Adverse Events of Special Interest (AESIs) Were Reported

- **FDA AESIs (both age groups):**
  - Predominant categories were potential angioedema and hypersensitivity comprising mainly urticarias and rashes
  - Similar incidence between BNT162b2 and placebo for these categories
- **CDC Defined AESIs:**
  - No vaccine related anaphylaxis
  - No myocarditis/pericarditis
  - No Bell's palsy (or facial paralysis/paresis)
  - No MIS-C

AGE
6 mo. to <5

Favorable Safety Profile and Well-tolerated

Phase 2/3 Safety Population (N=4,526)

- **Vaccine reactions were mostly mild to moderate and short lived, with systemic reactions comparable to placebo**
- **Reactions were comparable after dose 1, 2, and 3**
- **The unsolicited AE profile mostly reflected reactogenicity or common childhood illnesses**
- **Safety assessment demonstrates a safe and well tolerated vaccine that should encourage use**

Immunogenicity

AGE
2 to <5

Immunobridging Criteria Met for Both GMR and Seroresponse in Participants Without Prior Infection

Post-dose 3 Compared to 16 to 25 Years of Age Post-dose 2

	BNT162b2 (3 µg) 2 to <5 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		2 to <5 / 16-25 years	
GMR	**n**	**GMT (95% CI)**	**n**	**GMT (95% CI)**	**GMR (95% CI)**	**Met Criteria (Y/N)**
SARS-CoV-2 neutralization assay - NT50 (titer)	**143**	**1535.2 (1388.2, 1697.8)**	**170**	**1180.0 (1066.6, 1305.4)**	**1.30 (1.13, 1.50)**	**Y**

Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8 and ≥1 per FDA criteria

AGE
2 to <5

Immunobridging Criteria Met for Both GMR and Seroresponse in Participants Without Prior Infection

Post-dose 3 Compared to 16 to 25 Years of Age Post-dose 2

	BNT162b2 (3 µg) 2 to <5 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		2 to <5 / 16-25 years	
GMR	n	GMT (95% CI)	n	GMT (95% CI)	GMR (95% CI)	Met Criteria (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	143	1535.2 (1388.2, 1697.8)	170	1180.0 (1066.6, 1305.4)	1.30 (1.13, 1.50)	Y

Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8 and ≥1 per FDA criteria

	BNT162b2 (3 µg) 2 to <5 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		Difference in % 2 to <5 - 16-25 years	
Seroresponse	**N**	**n (%) (95% CI)**	**N**	**n (%) (95% CI)**	**% (95% CI)**	**Met Criteria (Y/N)**
SARS-CoV-2 neutralization assay - NT50 (titer)	**141**	**141 (100.0) (97.4, 100.0)**	**170**	**168 (98.8) (95.8, 99.9)**	**1.2 (-1.5, 4.2)**	**Y**

Seroresponse defined as achieving a ≥4 fold rise from baseline (before Dose 1).
Immunobridging is declared if the lower bound of the 95% confidence interval for the percentage difference is greater than -10

AGE
6 mo. to <2

Immunobridging Criteria Met for Both GMR and Seroresponse in Participants Without Prior Infection

Post-dose 3 Compared to 16 to 25 Years of Age Post-dose 2

	BNT162b2 (3 µg) 6M to <2 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		6M to <2 / 16-25 years	
GMR	n	GMT (95% CI)	n	GMT (95% CI)	GMR (95% CI)	Met Criteria (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	82	1406.5 (1211.3, 1633.1)	170	1180.0 (1066.6, 1305.4)	1.19 (1.00, 1.42)	Y

Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8 and ≥1 per FDA criteria

AGE
6 mo. to <2

Immunobridging Criteria Met for Both GMR and Seroresponse in Participants Without Prior Infection

Post-dose 3 Compared to 16 to 25 Years of Age Post-dose 2

	BNT162b2 (3 µg) 6M to <2 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		6M to <2 / 16-25 years	
GMR	n	GMT (95% CI)	n	GMT (95% CI)	GMR (95% CI)	Met Criteria (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	82	1406.5 (1211.3, 1633.1)	170	1180.0 (1066.6, 1305.4)	1.19 (1.00, 1.42)	Y

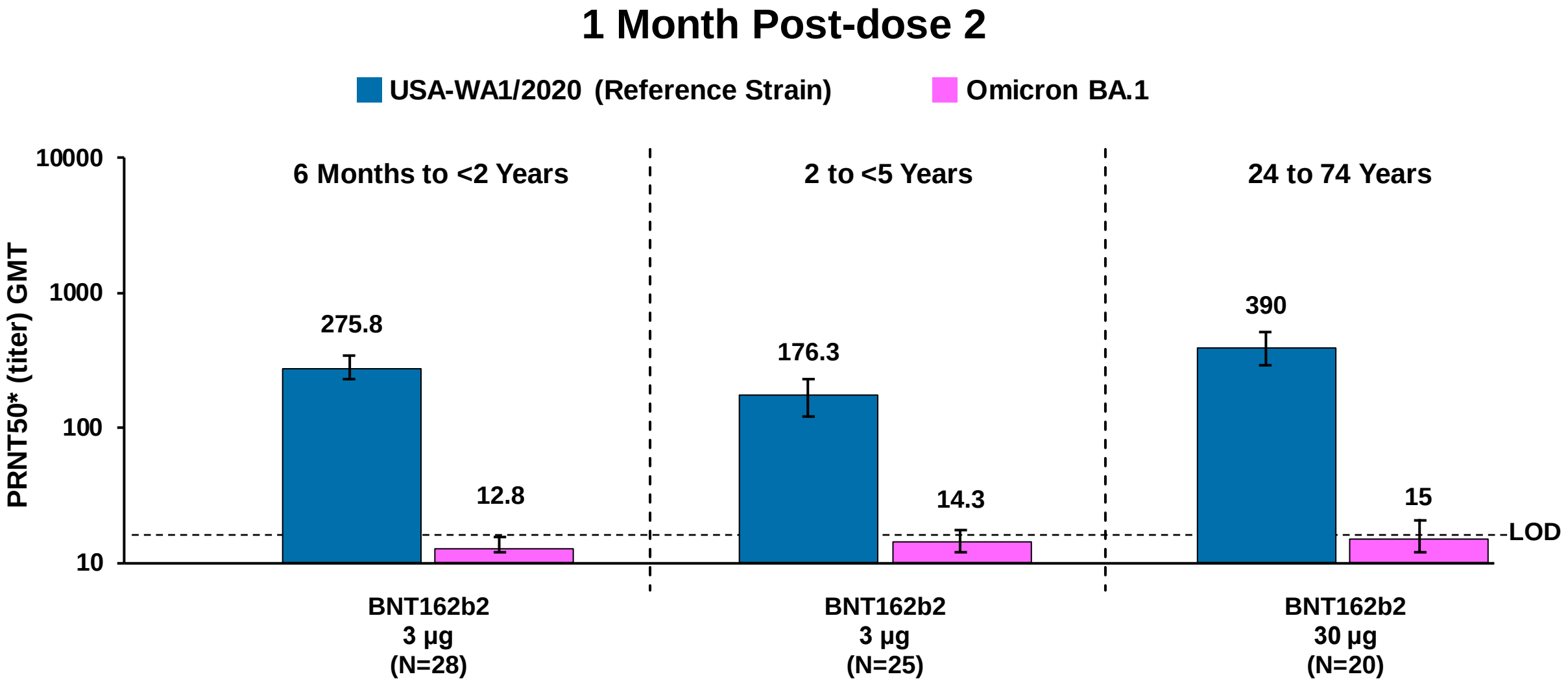
Immunobridging is declared if the lower bound of the 95% confidence interval of the GMR is > 0.67 and the GMR is ≥0.8 and ≥1 per FDA criteria

	BNT162b2 (3 µg) 6M to <2 Years 1M Post-Dose 3		BNT162b2 (30 µg) 16-25 years 1M Post-Dose 2		Difference in % 6M to <2 - 16-25 years	
Seroresponse	**N**	**n (%) (95% CI)**	**N**	**n (%) (95% CI)**	**% (95% CI)**	**Met Criteria (Y/N)**
SARS-CoV-2 neutralization assay - NT50 (titer)	**80**	**80 (100.0) (95.5, 100.0)**	**170**	**168 (98.8) (95.8, 99.9)**	**1.2 (-3.4, 4.2)**	**Y**

Seroresponse defined as achieving a ≥4 fold rise from baseline (before Dose 1).
Immunobridging is declared if the lower bound of the 95% confidence interval for the percentage difference is greater than -10

AGE
6 mo. to <5

Robust Immune Response After 2 Doses to Reference Strain with Low Immune Responses to Omicron



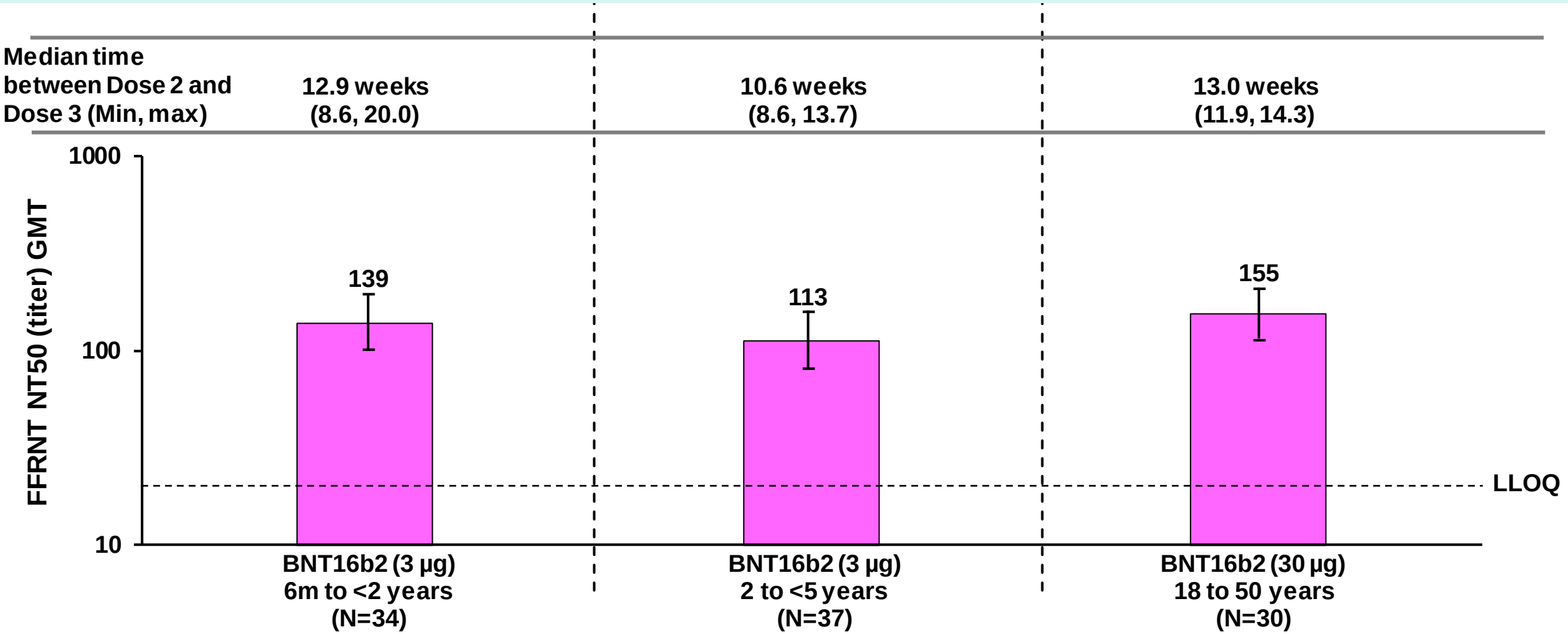
*PRNT50 = 50% Plaque Reducing neutralizing titers

CC-30

AGE
6 mo. to <5

Similar Neutralizing Responses to Omicron Observed Across Age Groups One Month After The 3rd Dose

Subjects WITHOUT evidence of existing or preexisting SARS-CoV-2 infection



AGE
6 mo. to <5

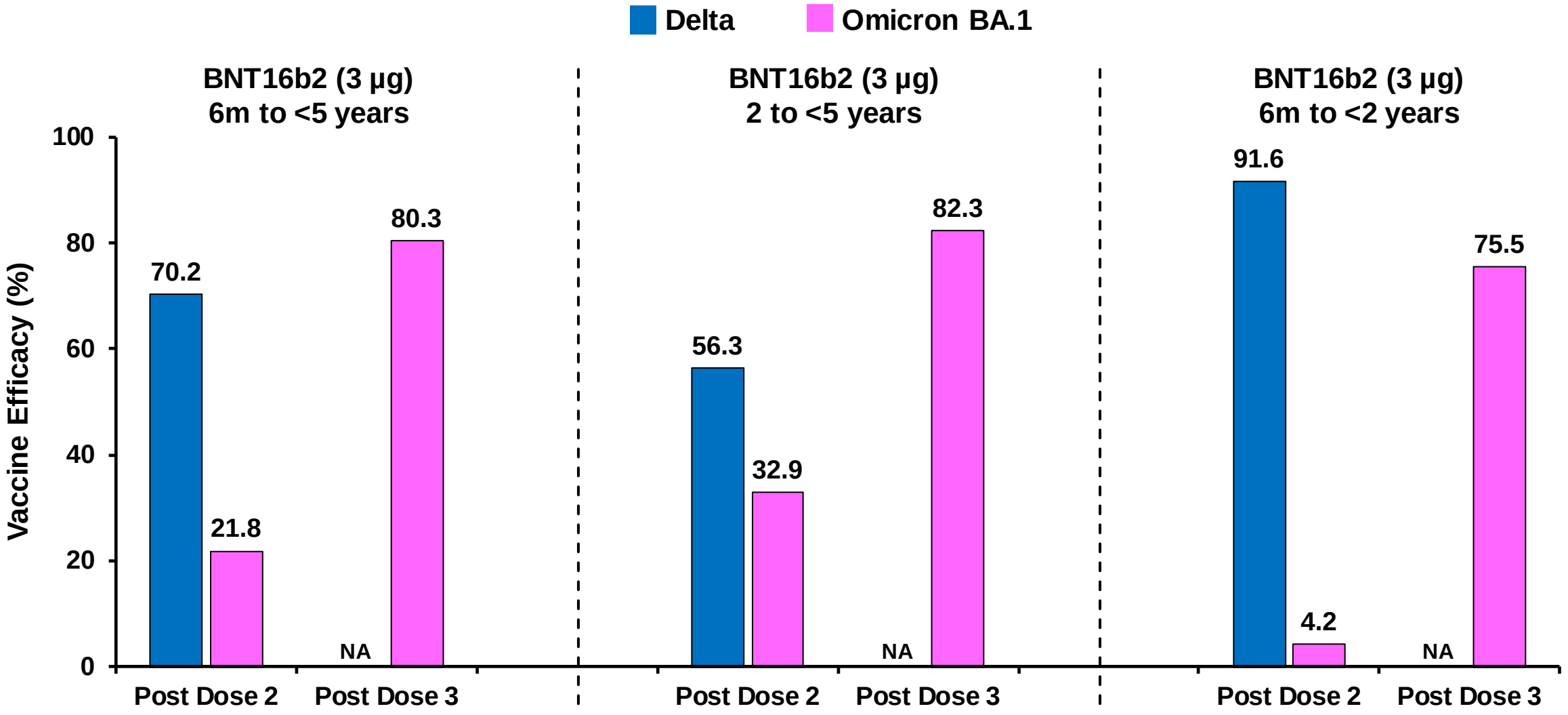
Immunogenicity Conclusions

- **Immunobridging criteria (post-dose 3 in young children to post-dose 2 in young adults) were met for both age groups**
- **Omicron neutralizing titers were much higher after the 3rd dose**
- **As has been observed in other populations, a 3rd dose in young children is likely to be associated with high protection against COVID-19 due to Omicron**

Efficacy

AGE
6 mo. to <5

High Observed Efficacy After 3rd Dose Against Omicron



NA - Not applicable as Delta cases post Dose 3 did not occur during this time period.

AGE
6 mo. to <5

Vaccine Efficacy 80% Post-dose 3 During a Period When Omicron Was Predominant

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 3

	BNT162b2 (3 µg)		Placebo			
	n / N	Surveillance Time (n)	n / N	Surveillance Time (n)	VE (%)	(95% CI)
6 months to <5 years	3 / 992	0.086 (758)	7 / 464	0.039 (348)	80.3	(13.9, 96.7)
2 to <5 years	2 / 606	0.056 (481)	5 / 280	0.025 (209)	82.3	(-8.0, 98.3)
6 months to <2 years	1 / 386	0.030 (277)	2 / 184	0.015 (139)	75.5	(-370.1, 99.6)

All the cases post-dose 3 were after February 7, 2022 when >98%[a] of all samples globally were omicron

Weekly epidemiological update on COVID-19 - 15 February 2022; Edition 79 15 February 2022; Emergency Situational Updates
https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---15-february-2022
Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint

AGE
6 mo. to <5

Descriptive Efficacy Conclusions

- **As demonstrated in other pediatric and adult age groups, two doses of BNT162b2 are protective against variants of concern such as Delta, but do not provide adequate protection against Omicron**

- **As demonstrated in other pediatric and adult age groups, a third dose is necessary to provide high protection against Omicron**

Ongoing and Active Pharmacovigilance and Pharmacoepidemiology (Pediatric)

Pharmacoepidemiology Studies for Ages 6 Months and Up

5 Studies that include pediatric patients:

- >100M persons in source populations
- All evaluate post-vaccination myocarditis
- 4 evaluate long-term sequelae outcomes

Proactive Risk Mitigation

- Labeling
- Educational materials
- Vial differentiation

Pharmacovigilance

- **Detect unexpected safety events rapidly**
- Spontaneous report collection
- Active follow-up
- Frequent signal detection and evaluation

Potential Benefits of Vaccinating Children 6m to <5y of Age Outweigh Known/Potential Risks

- **Children 6 months to <5 years of age are currently unprotected**
- **Protection against COVID-19 is critical – particularly given the unpredictability of future waves or emergence of new variants**
- **Available safety, immunogenicity, and efficacy data support a favorable benefit-risk profile for administration of 3 doses of BNT162b2 at 3µg to children 6 months to <5 years of age**

Pfizer/BioNTech requests EUA of BNT162b2 3 µg for active immunization of individuals 6 Months through 4 years of age, administered intramuscularly as a primary three-dose series.

Acknowledgments

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- **The clinical trial participants and their families**
- **Sites, investigators, CRO, our partners and their staff**
- **FDA guidance to assess this urgent medical need**

BNT162b2 (COVID-19 Vaccine, mRNA) Request for Emergency Use Authorization in Individuals 6 Months Through 4 Years of Age

Vaccines and Related Biological Products Advisory Committee

June 15, 2022

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