BNT162b2 (COVID-19 Vaccine, mRNA) Vaccine – in Individuals 5 to <12 Years of Age

Alejandra Gurtman, MD
Vice President
Vaccine Clinical Research and Development
Pfizer Inc

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Presentation Agenda

Introduction

Clinical Data
- Phase 2/3 Immunogenicity and Safety
- Efficacy Analysis
Pfizer/BNT Received Emergency Use Authorization of 10ug Dose of BNT162 in Children 5 to <12 Years of Age

10ug dose level was selected as optimal to elicit robust immune responses with an acceptable safety profile

Proposed Indication and Schedule

| Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 5 to <12 years of age | Administered intramuscularly as a primary series of 2 doses (0.2 mL each), 3 weeks apart |
BNT162b2 – Meets EUA Guidance for 5 to <12 Years of Age

Clear and Compelling Data

- Meets all safety data expectations for follow up durations and subject number
- Meets Immunobridging criteria comparing 5 to <12 yo to 16 to 25 yo subjects
- 90.7% efficacy was observed
- Plans for active safety follow up under EUA
- Vaccine’s benefits outweigh its risks
Clinical Data
# Pfizer-BioNTech Pediatric COVID-19 Vaccine

## BNT162b2: Study Overview: 5 to <12 Years

### Phase 1
- **48 PARTICIPANTS**
  - 5 to <12 yrs
- Identification of preferred dose level(s)
  - 10 µg
  - 20 µg
  - 30 µg

### Phase 2/3
- **2:1 randomization**
- ~1500 BNT162b2
- 750 placebo

- ~Additional 1500 BNT162b2 and 750 placebo recipients most with ≥2 weeks post dose 2 safety data

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

<table>
<thead>
<tr>
<th>Children 5 to &lt;12 years of age</th>
<th>Compared to 16–25-year-olds from the pivotal Phase 3 study</th>
</tr>
</thead>
</table>

Although not required for EUA approval, COVID-19 surveillance was conducted permitting evaluation of vaccine efficacy.
Phase 2/3 Timelines of Participants 5 to <12 Years of Age Through 6 Months Post-dose 2

7 DAY Reactogenicity

V1 Dose 1
V2 Dose 2
V3
V4 1mo
V5 6mo

NON-SERIOUS AEs ICD to Visit 4 (1-Month follow-up)

SERIOUS AEs ICD to Visit 5 (6-Month follow-up)

Blood draws for Immunogenicity

COVID-19/MIS-C Visit: triggered if a participant reports experiencing a COVID-19/MIS-C Symptom reported on the Illness diary or reported directly by the participants → potential COVID-19 Illness visit (telehealth/in-person visit + nasal swab) must be scheduled (optimally within 3 Days after illness onset)
Safety Data for 5 to <12 Year Olds to Support EUA Application

- **Initial enrollment group**: 2268 participants
- **Safety expansion group**: 2379 participants

**Median follow-up time**
- Initial enrollment group: 2.3 months
- Safety expansion group: 2.4 weeks

**Additional follow-up time**: 3.3 months
## Demographics for 5 to <12 Year Olds

### Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2 (10µg) N=1518</th>
<th>Placebo N=750</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>799 (52.6)</td>
<td>383 (51.1)</td>
</tr>
<tr>
<td>Female</td>
<td>719 (47.4)</td>
<td>367 (48.9)</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1204 (79.3)</td>
<td>586 (78.1)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>89 (5.9)</td>
<td>58 (7.7)</td>
</tr>
<tr>
<td>American Indian or Alaska native</td>
<td>12 (0.8)</td>
<td>3 (0.4)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Asian</td>
<td>90 (5.9)</td>
<td>47 (6.3)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>109 (7.2)</td>
<td>49 (6.5)</td>
</tr>
<tr>
<td>Not reported</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td><strong>Ethnicity, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>319 (21.0)</td>
<td>159 (21.2)</td>
</tr>
<tr>
<td>Non-Hispanic/non-Latino</td>
<td>1196 (78.8)</td>
<td>591 (78.8)</td>
</tr>
<tr>
<td>Not reported</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td><strong>Age at vaccination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>8.2 (1.93)</td>
<td>8.1 (1.97)</td>
</tr>
<tr>
<td>Min, Max</td>
<td>(5, 11)</td>
<td>(5, 11)</td>
</tr>
<tr>
<td><strong>Obese, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>174 (11.5)</td>
<td>92 (12.3)</td>
</tr>
<tr>
<td><strong>Comorbidities(^a), n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>312 (20.6)</td>
<td>152 (20.3)</td>
</tr>
</tbody>
</table>

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\(a\). Participants who had at least one of the prespecified comorbidities based on MMWR 69(32):1081-1088 and/or obesity (BMI ≥ 95th percentile)  
\(b\). 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](https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm).
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds

Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 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: 5-<12 yrs N=2260; 16-25 yrs N=1064   Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

Redness
- Dose 1: 10 µg 5-<12 yrs 14.7% redness, 0.9% severe; 16-25 yrs 10.5% redness, 1.1% severe
- Dose 2: 10 µg 5-<12 yrs 18.5% redness, 0.2% severe; 16-25 yrs 15.3% redness, 0.2% severe

Swelling
- Dose 1: 10 µg 5-<12 yrs 2.7% swelling, 1.1% severe; 16-25 yrs 8.3% swelling, 1.1% severe
- Dose 2: 10 µg 5-<12 yrs 2.7% swelling, 0.2% severe; 16-25 yrs 6.8% swelling, 0.2% severe

Pain at Injection Site
- Dose 1: 10 µg 5-<12 yrs 74.1% pain, 15.9% severe; 16-25 yrs 83.4% pain, 15.9% severe
- Dose 2: 10 µg 5-<12 yrs 71.0% pain, 12.1% severe; 16-25 yrs 77.5% pain, 12.1% severe

Redness and swelling severity definition: Mild= >2-5 cm, Moderate= >5-10 cm; Severe= >10 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: 5-<12 yrs N=2260; 16-25 yrs N=1064   Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984
Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 and 16-25 Year Olds

<table>
<thead>
<tr>
<th>Fatigue</th>
<th>Headache</th>
<th>Chills</th>
<th>Vomiting</th>
<th>Diarrhea</th>
<th>Muscle Pain</th>
<th>Joint Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>38.0 °C-38.4 °C</td>
<td>38.4 °C-38.9 °C</td>
<td>38.9 °C-40.0 °C</td>
<td>&gt;40.0 °C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-12 µg</td>
<td>10 µg</td>
<td>16-25 µg</td>
<td>30 µg</td>
<td>5-12 µg</td>
<td>10 µg</td>
<td>16-25 µg</td>
</tr>
<tr>
<td>6.5%</td>
<td>39.4%</td>
<td>28.0%</td>
<td>4.0%</td>
<td>5.3%</td>
<td>11.7%</td>
<td></td>
</tr>
<tr>
<td>17.2%</td>
<td>40.0%</td>
<td>9.8%</td>
<td>8.0%</td>
<td>40.8%</td>
<td>4.3%</td>
<td></td>
</tr>
<tr>
<td>5-12 µg</td>
<td>10 µg</td>
<td>16-25 µg</td>
<td>30 µg</td>
<td>5-12 µg</td>
<td>10 µg</td>
<td>16-25 µg</td>
</tr>
<tr>
<td>1.2%</td>
<td>1.8%</td>
<td>5.2%</td>
<td>9.7%</td>
<td>3.6%</td>
<td>4.0%</td>
<td></td>
</tr>
</tbody>
</table>

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 times 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 2: 5-12 yrs N=2242 16-25 yrs N=984

CC-11
Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status

<table>
<thead>
<tr>
<th></th>
<th>Dose 1</th>
<th></th>
<th>Dose 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td></td>
<td>Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 µg</td>
<td>Placebo</td>
<td>10 µg</td>
<td>Placebo</td>
</tr>
<tr>
<td>Redness</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
<td>Grade 4</td>
</tr>
<tr>
<td>Grade 1</td>
<td>15.0%</td>
<td>7.7%</td>
<td>14.7%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Grade 2</td>
<td>9.9%</td>
<td>3.1%</td>
<td>19.3%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 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: Positive N=198; Negative N=2062  Dose 2: Positive N=195; Negative N=2047
Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 and Dose 2 in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status

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 times 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 Positive  N=198; Negative N=2062  Dose 2: Positive N=195; Negative N=2047
Adverse Events
Overall Adverse Events from Dose 1 to Data Cutoff Date: 5 to <12 Year Olds

Initial enrollment group: Median follow-up time 2.3 months Cutoff date September 6, 2021

Safety expansion group: Median follow-up time 2.4 weeks Cutoff date October 8, 2021
Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Initial Enrollment Group (N=2268)

- Predominantly reflect nausea, vomiting and diarrhea
- Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue

Lymphadenopathy 0.9% in BNT162b2 group

Data Cutoff September 6, 2021

- Any adverse events
- Infections and infestations
- Injury, poisoning and procedural complications
- Gastrointestinal disorders
- Respiratory, thoracic and mediastinal disorders
- General disorders and administration site conditions
- Skin and subcutaneous tissue disorders

Percent of Subjects Reporting ≥1 AE

- BNT162b2 10μg (N=1518)
- Placebo (N=750)

- Predominantly reflect nausea, vomiting and diarrhea
- Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue

Lymphadenopathy 0.9% in BNT162b2 group
Adverse Events ≥1.0% by System Organ Class for 5 to <12 Year Olds from Dose 1 to Cutoff Date Safety Expansion Group (N= 2379)

1. Predominantly reflect local reactions at the injection site and systemic reactions of fatigue
2. Lymphadenopathy 0.4% in the BNT162b2 group

Data Cutoff October 8, 2021

- Any adverse events: BNT162b2 10μg (N=1591) 7.2% vs Placebo (N=788) 6.3%
- General disorders and administration site conditions: BNT162b2 10μg (N=1591) 2.3% vs Placebo (N=788) 1.8%
- Skin and subcutaneous tissue disorders: BNT162b2 10μg (N=1591) 1.0% vs Placebo (N=788) 0.5%
- Respiratory, thoracic and mediastinal disorders: BNT162b2 10μg (N=1591) 0.9% vs Placebo (N=788) 1.3%
- Injury, poisoning and procedural complications: BNT162b2 10μg (N=1591) 0.5% vs Placebo (N=788) 1.0%
Overall Adverse Events from Dose 1 to 1 Month Post Dose 2 in 5 to <12 Year Olds by Baseline SARS-CoV-2 Status

Baseline SARS-CoV-2 Positive

Baseline SARS-CoV-2 Negative
Serious Adverse Events from Dose 1 to Cutoff Date in 5 to <12 Year Olds

- **Initial enrollment group (all unrelated):**
  - One participant in the BNT162b2 group reported a SAE of an upper limb fracture
  - One participant in the Placebo group reported a SAE of abdominal pain and a SAE of pancreatitis related to trauma

- **Expansion Safety group (all unrelated; all in the BNT162b2 group):**
  - One participant reported a SAE of infective arthritis
  - One participant reported a SAE of epiphyseal fracture
  - One participant reported a SAE of ingestion of a foreign body
Adverse Events of Special Interest
Initial Enrollment Group and Safety Expanded Group

• FDA AESIs:
  – No anaphylaxis
  – No myocarditis/pericarditis
  – No Bell’s palsy (or facial paralysis/paresis)
  – No appendicitis

• CDC Defined AESIs:
  – Potential hypersensitivity (angioedema, and predominantly rash and urticaria)
  – Arthritis (infective)
  – Vasculitis
Safety Conclusions for 5 to <12 Year Olds

- Reactogenicity was mostly mild to moderate, and short lived
- Observed mild to moderate local reactions (redness, swelling) captured by ediyary were more common and systemic reactions (including fever) less common than those in 16-25 year olds
- The observed AE profile in this study did not suggest any safety concerns for BNT162b2 vaccination in children 5 to <12 years of age
Immunogenicity and Efficacy
## Immunobridging Criteria Between 5 to <12 and 16-25 Years of Age Were Met Both for GMR and for Seroresponse

<table>
<thead>
<tr>
<th>Assay</th>
<th>Dosing/Sampling Time Point</th>
<th>5 to &lt;12 / 16-25 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BNT162b2 (10µg) 5 to &lt;12 Years</td>
</tr>
<tr>
<td></td>
<td>n (95% CI)</td>
<td>n (95% CI)</td>
</tr>
<tr>
<td>SARS-CoV-2 neutralization assay - NT50 (titer)</td>
<td>2 / 1 Month</td>
<td>264 (1197.6, 1106.1, 1296.6)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Assay</th>
<th>Dosing/Sampling Time Point</th>
<th>5 to &lt;12 / 16-25 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BNT162b2 (10µg) 5 to &lt;12 Years</td>
</tr>
<tr>
<td></td>
<td>N (95% CI)</td>
<td>N (95% CI)</td>
</tr>
<tr>
<td>SARS-CoV-2 neutralization assay - NT50 (titer)</td>
<td>2 / 1 Month</td>
<td>264 (262 (99.2), 97.3, 99.9)</td>
</tr>
</tbody>
</table>

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

CC-23
**Geometric Mean Titers (NT50), By Baseline SARS-CoV-2 Status – Subjects 5 to <12 Years – Evaluable Immunogenicity Population Immunogenicity Subset**

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>SARS-Co-V-2 Positive</th>
<th>SARS-Co-V-2 Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMFR (95% CI)</td>
<td>113.1 (104.4, 122.6)</td>
<td>54.7 (35.3, 84.7)</td>
<td>119.6 (110.8, 129.2)</td>
</tr>
<tr>
<td>NT50 (titer) GMT</td>
<td>1300.3</td>
<td>3270.0</td>
<td>1211.3</td>
</tr>
<tr>
<td>N=294</td>
<td>N=294</td>
<td>N=21</td>
<td>N=273</td>
</tr>
<tr>
<td>BNT162b2 10 µg</td>
<td>11.5</td>
<td>59.8</td>
<td>10.1</td>
</tr>
<tr>
<td>Day 1</td>
<td>1M PD2</td>
<td>Day 1</td>
<td>1M PD2</td>
</tr>
<tr>
<td></td>
<td>10,000</td>
<td>1000</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td>1000</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

NT50 = 50% neutralizing titers
Geometric Mean Titers (NT50), by Age Subgroup – Subjects 5 to <12 Years – Evaluable Immunogenicity Population

Immunogenicity Subset – Without Evidence of Prior Infection up to 1 Month Post Dose 2

NT50 (titer) GMT

<table>
<thead>
<tr>
<th>Group</th>
<th>Day 1</th>
<th>1M PD2</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>10.1</td>
<td>N=264</td>
</tr>
<tr>
<td>5-6 Years</td>
<td>10.0</td>
<td>N=59</td>
</tr>
<tr>
<td>7-8 Years</td>
<td>10.0</td>
<td>N=74</td>
</tr>
<tr>
<td>9-11 Years</td>
<td>10.3</td>
<td>N=131</td>
</tr>
</tbody>
</table>

NT50 = 50% neutralizing titers
Neutralization of Both Reference Strain and Delta Variant of Concern are Comparable – Randomly Selected Subset
Phase 2/3 - Subjects 5 to <12 Years of Age

<table>
<thead>
<tr>
<th></th>
<th>Reference Strain (USA-WA1/2020)</th>
<th>Delta Strain (B.1.617.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BNT162b2 (10 µg)</td>
<td>BNT162b2 (10 µg)</td>
</tr>
<tr>
<td>GMFR (95% CI)</td>
<td>36.5 (27.9, 47.8)</td>
<td>29.5 (21.5, 40.5)</td>
</tr>
</tbody>
</table>

Plaque Reduction Neutralization NT50 (titer) GMT

- Day 1: Reference Strain 10.0, Delta Strain 10.0
- 1M PD2: Reference Strain 365.3, Delta Strain 294.9
High Efficacy was Observed in 5 to <12 Year Olds Descriptive Analysis of First COVID-19 Occurrence From 7 Days After Dose 2

Subjects WITHOUT Evidence of Infection Prior to 7 Days After Dose 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (10 µg) N=1305</th>
<th>Placebo N=663</th>
<th>VE (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First COVID-19 occurrence ≥7 days after Dose 2</td>
<td>3 (0.322 (1273))</td>
<td>16 (0.159 (637))</td>
<td>90.7 (67.7, 98.3)</td>
</tr>
</tbody>
</table>

No severe cases of COVID-19 were reported
No cases of MIS-C were reported

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint
Cumulative Incidence of COVID-19 After Dose 1: 5 to <12 Years of Age

Days After Dose 1

Cumulative Incidence of COVID-19 Occurrence

Placebo

BNT162b2 (10 μg)
Immunogenicity and Efficacy Conclusions

• Immunobridging success criteria were met for 5 to <12 year olds at 10 µg dose level

• BNT162b2-immune sera effectively neutralized both USA-WA1/2020 (reference strain) and the highly transmissible B.1.617.2 (Delta) variant of concern

• BNT162b2 as a two dose series is highly protective against COVID-19 in 5 to <12 year olds when Delta variant was prominent
Ongoing and Active Pharmacovigilance and Pharmacoepidemiology (Pediatric)

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

Proactive Risk Mitigation
- Labeling
- Educational materials
- Vial differentiation

Pharmacoepidemiology Studies
- 5 Studies that include pediatric patients:
  - 3 studies of >175M health records
  - 2 studies of post-vaccination myocarditis
Acknowledgments

Pfizer and BioNTech wish to thank:

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