COVID-19 Vaccine
BNT162b2 update

Presentation to the WHO
Scientific Advisory Group of
Experts (SAGE)
27 May 2021

Dr. Luis Jodar
SVP and CMO, Pfizer
Vaccines on behalf of
BionTech and Pfizer
# Pfizer and BioNTech Attendees

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Department</th>
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<tbody>
<tr>
<td>Dr. Luis Jodar</td>
<td>Chief medical Officer, Pfizer Vaccines</td>
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<tr>
<td>Dr. Phil Dormitzer</td>
<td>Chief Scientific Officer– Pfizer Viral Vaccines</td>
</tr>
<tr>
<td>Dr. John Perez</td>
<td>Pfizer Vaccines Clinical Research &amp; Development</td>
</tr>
<tr>
<td>Dr. Steve Lockhart</td>
<td>Pfizer COVID Vaccine Clinical Lead</td>
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<td>Dr. Susan Mather</td>
<td>Pfizer Safety Surveillance &amp; Risk Management</td>
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<td>Dr. Dina Tresnan</td>
<td>Pfizer Safety Surveillance &amp; Risk Management</td>
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<td>Dr. Christian Lenz</td>
<td>Pfizer COVID Medical Lead, IDM</td>
</tr>
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<td>Dr. Donna Boyce</td>
<td>Pfizer Head of Regulatory Affairs, Vaccines</td>
</tr>
<tr>
<td>Dr. Özlem Türeci</td>
<td>Chief Medical Officer BioNTech</td>
</tr>
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<td>Dr. Eleni Lagkadinou</td>
<td>Clinical Development BioNTech</td>
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<td>Dr. Shanti Pather</td>
<td>Global Medical Affairs BioNTech</td>
</tr>
<tr>
<td>Dr. Anoop Sagar</td>
<td>Global Medical Affairs BioNTech</td>
</tr>
<tr>
<td>Dr. Alexander Crocker-Buque</td>
<td>Global Medical Affairs BioNTech</td>
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<td>Dr. Valeska Scharen-Guivel</td>
<td>Global Medical Affairs BioNTech</td>
</tr>
<tr>
<td>Dr. Ruben Rizzi</td>
<td>Global Regulatory Affairs BioNTech</td>
</tr>
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</table>
Agenda

• BNT162b2 vaccine update on VOC and booster plans

• Safety, Immunogenicity and Efficacy of BNT162b2 vaccine in 12-15 years old
BNT162b2 vaccine update on VOC and booster plans
BNT162b2 Vaccine

Proposed Indication:
Prevention of Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2

Individuals 12 years of age and older (FDA EUA)

Dose Level and Regimen
- 30 µg
- 2 doses given greater than or equal to 21 days apart

Presentation
- 6 dose multidose vial

Storage
- -80°C to -60°C up to 6 months
- -15°C to -25°C up to 2 weeks
- 2°C-8°C up to 31 days
Subjects in Pivotal Phase 2/3 Study

• \(~46,000\) healthy subjects enrollment target
  – Stable chronic disease allowed
  – Stable HIV, HBV, HCV

• At least 40% ages 56 years or older

• Balanced racial and ethnicity profile
  – Black/African American
  – Asian
  – Hispanic/Latinx

• Immunocompromised excluded

Limited number of 12-15 yo not part of EUA application
Phase 2/3 Safety/Efficacy Schema – Started 27 July, 2020

**Vaccination period**
- 21 days apart

**Follow-up period**
- Up to 2 years

**Active surveillance**
for potential COVID-19 symptoms TRIGGERING telehealth or in-person visit and nasal swab

- 7 days
- Reactogenicity in subsets for 16 and above; all 12-15 year olds
- 7 days
- Non-serious AE: all participants
- One month post dose 2
- Six months post dose 2
- Serious AE: all participants
- Through study
- Deaths: all participants

The first primary efficacy endpoint evaluation, individuals with NO evidence of prior/ current infection before each dose. Determined by a swab at the time of each dose and evidence of COVID by PCR or by obtaining blood specimen for N-antigen antibodies at the time of the first dose to indicate evidence of prior infection.
BioNTech/Pfizer vaccine efficacy remains high up to 6 Months following 2nd dose
Subjects Without Evidence of Infection Prior to 7 days after Dose 2 (C4591001)

The landmark trial enrolled 46,331 participants at 153 clinical sites around the world

<table>
<thead>
<tr>
<th>Subjects 16 – 85 Years of Age</th>
<th>BNT162b2 (30 µg) N=20,998</th>
<th>Placebo N=21,096</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy Endpoint</td>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>First COVID-19 occurrence &gt;7 days after Dose 2</td>
<td>77 6.247 (20712)</td>
<td>850 6.003 (20713)</td>
</tr>
<tr>
<td>First Severe COVID-19 occurrence &gt;7 days after Dose 2</td>
<td>0* 6.250 (20688)</td>
<td>32 6.108 (20680)</td>
</tr>
</tbody>
</table>

*Based on CDC definitions; 1 severe case observed in vaccine group based on FDA definition
Neutralization of SARS-CoV2 emerging variants by BNT162b2-elicited sera

BNT162b2 mRNA vaccine immune sera (n=15 participants) tested against 5 recombinant viruses covering key variants B.1.1.7, B.1.351, P.1. vs. the wildtype Wa-1 genetic background

- B.1.1.7-spike and P.1-spike virus neutralization was roughly equivalent
- B.1.351-spike virus neutralization still robust but ~2.7-fold lower
- Mutations in receptor binding site (K417N, E484K, N501Y) affect neutralization more than 242-244 deletion in spike N-terminal domain

Reduced variant neutralization titers are much higher than the barely detectable titers observed after 1 dose of BNT162b2, when strong efficacy was already observed in pivotal Ph 3 trial

100% Observed Efficacy of BNT162b2 Against B.1.351 in a Sub-Analysis of Data from South Africa

- The vaccine efficacy estimate for B.1.351 was part of the pivotal phase 2/3 clinical study with a cut-off date of 13 March and was calculated in a sub-analysis at the South African site of the pivotal phase 2/3 trial.
- There were 291 vaccinated with BNT162b2 and 276 received placebo.
- 9 cases of COVID-19 observed without evidence of prior SAR-CoV-2 infection
- Case split: BNT162b2 – 0, placebo – 9
- Nasal swabs from 8 of the cases yielded viral sequence of B.1.351
- Observed vaccine efficacy against B.1.351 in the South Africa sub-analysis = 100% (95% CI [53.5, 100.0])
Neutralization of SARS-CoV2 emerging variants by BNT162b2-elicited sera

USA-WA1/2020 – wild type virus; B.1.525-spike – Nigerian variant virus; B.1.617-1, B.1.617-2, B.1.617.2-vs, B.1.618 – Indian variant viruses
# Real world effectiveness against B.1.1.7 and B.1.617.2 in the UK

## Table 2: Vaccine effectiveness against S-gene target negative (B.1.1.7) and S-gene target positive (B.1.617.2)

<table>
<thead>
<tr>
<th>Vaccination status</th>
<th>Test negative controls</th>
<th>B.1.1.7 or S-gene target negative</th>
<th>B.1.617.2 or S-gene target positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>cases</td>
<td>cases:controls</td>
<td>aVE(%)</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>58253</td>
<td>4891</td>
<td>0.084 (base)</td>
</tr>
<tr>
<td>Any vaccine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>32703</td>
<td>1481</td>
<td>0.045 (51.1 (47.3 to 54.7))</td>
</tr>
<tr>
<td>Dose 2</td>
<td>8483</td>
<td>74</td>
<td>0.009 (86.8 (83.1 to 89.6))</td>
</tr>
<tr>
<td>BNT162b2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose 1</td>
<td>7036</td>
<td>344</td>
<td>0.049 (49.2 (42.6 to 55.0))</td>
</tr>
<tr>
<td>Dose 2</td>
<td>6412</td>
<td>28</td>
<td>0.004 (93.4 (90.4 to 95.5))</td>
</tr>
</tbody>
</table>

From Bernal et al., medRxiv 2021. DOI:10.1101/2021.05.22.21257658v1
Prototype clinical study evaluating updated variant of concern vaccine and booster with current vaccine

<table>
<thead>
<tr>
<th>BNT162b2-experienced</th>
<th>Day 1</th>
<th>Day 7</th>
<th>Month 1</th>
<th>Month 6</th>
<th>Month 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Current vaccine</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
</tr>
<tr>
<td>2  Updated vaccine</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
</tr>
</tbody>
</table>

* After unblinding, a subset of participants will receive a 2nd dose of BNT162b2\textsubscript{VOC} at 1 month, with blood draws 7 days and 1 month later

<table>
<thead>
<tr>
<th>BNT162b2-naïve**</th>
<th>Day 1</th>
<th>Day 21</th>
<th>7 Days PD2</th>
<th>1 Month PD2</th>
<th>6 Months PD2</th>
<th>18 Months PD2</th>
</tr>
</thead>
<tbody>
<tr>
<td>3  Updated vaccine</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
<td>🎈</td>
</tr>
</tbody>
</table>

** COVID-19 vaccine-naïve and have not experienced COVID-19
PD2 = Post dose 2

This study is a pivotal non-inferiority study and is ongoing; data are not yet available

We have a process to be ready in less than 100 days to have a new variant vaccine, if needed, to start mass vaccination
Safety, Immunogenicity, and Efficacy of BNT162b2 in Subjects 12–15-years-old
Phase 2/3 Safety Schema – Started 27 July, 2020

**Vaccination period**

- 21 days apart

**Follow-up period**

- Up to 2 years

**Active surveillance**

for potential COVID-19 symptoms TRIGGERING
telehealth or in-person visit and nasal swab

- 7 days

- 7 days

- Reactogenicity in subsets for 16 and above; all 12-15 year olds

- 7 days

- Non-serious AE: all participants

- One month post dose 2

- Serious AE: all participants

- Six months post dose 2

- Deaths: all participants

**Through study**

- All 12-15 year olds had e-diaries to capture solicited events (N=2260)
- A random subset of 16-25 year olds had e-diaries (N=1097)
- Prior history of symptomatic COVID-19/MIS-C were excluded
## Demography for 12-15 and 16-25 year olds (Safety population)

<table>
<thead>
<tr>
<th></th>
<th>BNT162b2 12-15 Years (N=1131)</th>
<th>BNT162b2 16-25 Years (N=1867)</th>
<th>Placebo 12-15 Years (N=1129)</th>
<th>Placebo 16-25 Years (N=1903)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>567 (50.1)</td>
<td>921 (49.3)</td>
<td>585 (51.8)</td>
<td>882 (46.3)</td>
</tr>
<tr>
<td>Female</td>
<td>564 (49.9)</td>
<td>946 (50.7)</td>
<td>544 (48.2)</td>
<td>1021 (53.7)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>971 (85.9)</td>
<td>1443 (77.3)</td>
<td>962 (85.2)</td>
<td>1510 (79.3)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>52 (4.6)</td>
<td>189 (10.1)</td>
<td>57 (5.0)</td>
<td>179 (9.4)</td>
</tr>
<tr>
<td>American Indian or Alaska native</td>
<td>4 (0.4)</td>
<td>32 (1.7)</td>
<td>3 (0.3)</td>
<td>18 (0.9)</td>
</tr>
<tr>
<td>Asian</td>
<td>72 (6.4)</td>
<td>108 (5.8)</td>
<td>71 (6.3)</td>
<td>108 (5.7)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>3 (0.3)</td>
<td>10 (0.5)</td>
<td>0</td>
<td>3 (0.2)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>23 (2.0)</td>
<td>76 (4.1)</td>
<td>29 (2.6)</td>
<td>74 (3.9)</td>
</tr>
<tr>
<td>Not reported</td>
<td>6 (0.5)</td>
<td>9 (0.5)</td>
<td>7 (0.6)</td>
<td>11 (0.6)</td>
</tr>
<tr>
<td><strong>Racial desig.</strong></td>
<td>Japanese</td>
<td>5 (0.4)</td>
<td>3 (0.2)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>132 (11.7)</td>
<td>604 (32.4)</td>
<td>130 (11.5)</td>
<td>575 (30.2)</td>
</tr>
<tr>
<td>Non-Hispanic/non-Latino</td>
<td>997 (88.2)</td>
<td>1259 (67.4)</td>
<td>996 (88.2)</td>
<td>1322 (69.5)</td>
</tr>
<tr>
<td>Not reported</td>
<td>2 (0.2)</td>
<td>4 (0.2)</td>
<td>3 (0.3)</td>
<td>6 (0.3)</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td>USA</td>
<td>1131 (100.0)</td>
<td>1333 (71.4)</td>
<td>1129 (100.0)</td>
</tr>
<tr>
<td>Others*</td>
<td>0</td>
<td>534 (28.6)</td>
<td>0</td>
<td>539 (28.3)</td>
</tr>
</tbody>
</table>

*Note: All 12-15 year olds from the US; ~72% of 16-25 year olds from the US*

*Argentina, Brazil, Germany, South Africa, Turkey*
Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 12-15 and 16-25 Year Olds

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: 12-15 yrs N=2254; 16-25 yrs N=1084   Dose 2: 12-15 yrs N=2175 16-25 yrs N=984
Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 in 12-15 and 16-25 Year Olds

Fever:
- 38.0 °C-38.4 °C
- 38.4 °C-38.9 °C
- 38.9 °C-40.0 °C
- >40.0 °C

Fatigue:
- Mild: no interference; Moderate: some interference; Severe: prevents daily activity; Grade 4: ER visit or hospitalization

Headache:
- Mild: no interference; Moderate: some interference; Severe: prevents daily activity; Grade 4: ER visit or hospitalization

Chills:
- Mild: no interference; Moderate: some interference; Severe: prevents daily activity; Grade 4: ER visit or hospitalization

Vomiting:
- Mild: 1-2 times in 24h; Moderate: >2 times in 24h; Severe: Requires IV hydration; Grade 4: ER visit or hospitalization

Diarrhea:
- 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

A 14 year old in the BNT162b2 group had Grade 4 pyrexia (40.4 °C) on Day 2 after Dose 1, with temperature returning to normal within 2 days.

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: 12-15 yrs N=2254; 16-25 yrs N=1084
Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 12-15 and 16-25 Year Olds

**Systemic events:**
- **Mild**
- **Moderate**
- **Severe**
- **Grade 4**

**Fever:**
- 38.0 °C-38.4 °C
- 38.4 °C-38.9 °C
- 38.9 °C-40.0 °C
- >40.0 °C

**Fatigue, headache, chills, muscle pain, joint pain severity definition:**
- Mild=interference;
- Moderate=some interference;
- Severe=prevents daily activity;
- Grade 4=ER visit or hospitalization

**Vomiting severity definition:**
- Mild=1-2 time in 24h;
- Moderate=>2 times 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:**
- 12-15 yrs N=2175
- 16-25 yrs N=984

---

Fever
- BNT162b2: 19.6% 17.2%
- Placebo: 0.6% 0.4%

Fatigue
- BNT162b2: 66.2% 65.6%
- Placebo: 24.5% 23.2%

Headache
- BNT162b2: 64.5% 60.9%
- Placebo: 24.4% 23.8%

Chills
- BNT162b2: 41.5% 40.0%
- Placebo: 6.8% 4.4%

Vomiting
- BNT162b2: 2.6% 2.7%
- Placebo: 1.1% 1.8%

Diarrhea
- BNT162b2: 32.4% 40.8%
- Placebo: 4.0% 8.3%

Muscle Pain
- BNT162b2: 15.8% 21.9%
- Placebo: 4.7% 4.0%

Joint Pain
- BNT162b2: 19.6% 17.2%
- Placebo: 0.6% 0.4%
Overall Adverse Events from Dose 1 to 1 Month Post Dose 2
12-15 (N=2260) and 16-25 (Reactogenicity subset N=1097) year olds

- Overall, small number of adverse events: more in the 16-25 year olds
- Related AE due to reactogenicity events captured as AEs
- No related SAE’s
- No deaths
Adverse Events ≥1.0% by System Organ Class for 12-15 year olds from Dose 1 to Data Cut-off Date (13 Mar 2021)

The most frequently reported AEs in adolescents through the data cutoff date included lymphadenopathy (0.8%), injection site pain (0.6%), fatigue (0.6%), pyrexia (0.4%), nausea (0.4%), and headache (0.4%).

1. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue
2. Predominantly reflect nausea and diarrhea
3. Predominantly reflects Headache
# Serious Adverse Events by SOC/PT from Dose 1 to Data Cut-off Date 12-15 year olds

<table>
<thead>
<tr>
<th>System Organ Class/PT</th>
<th>BNT162b2 (30 μg) (N=1131)</th>
<th>Placebo (N=1129)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANY EVENT</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>GASTROINTESTINAL DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Abdominal pain</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>*Constipation</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>INFECTIONS AND INFESTATIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>#Appendicitis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>#Focal peritonitis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>NERVOUS SYSTEM DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Neuralgia</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>PSYCHIATRIC DISORDERS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>4</td>
<td>0.4</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3</td>
<td>0.3</td>
</tr>
<tr>
<td>Suicidal ideation</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>0.1</td>
</tr>
</tbody>
</table>

*Abdominal pain, constipation and neuralgia were in the same participant

#Appendicitis and focal peritonitis were in the same participant
Overall safety conclusions for 12-15 year olds

• **Reactogenicity:** BNT162b2 was well tolerated in subjects 12-15 years old and showed a similar pattern to that seen in 16-25 year olds
  - Pain at the injection site, fatigue, headaches, chills, joint pain and muscle pain were the most predominant as well as fever
  - Increased systemic events after dose 2 was similar to that seen with 16-25 year olds

• **Adverse events overall were few**
  - Highest incidence was in the General Disorders and Administration Site Conditions, reflecting local and systemic reactogenicity events
  - Lymphadenopathy was identified as related to vaccination
  - There were no related SAEs
  - No deaths were reported
Noninferiority Between 12-15 and 16-25 years Of Age Was Met Geometric Mean Ratio (GMR) in Neutralization Titers (Without prior infection)

<table>
<thead>
<tr>
<th>Assay</th>
<th>Dosing/ Sampling Time Point</th>
<th>BNT162b2 (30 µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 neutralization assay - NT50</td>
<td>2 / 1 Month</td>
<td>n</td>
</tr>
<tr>
<td>n</td>
<td>GMT (95% CI)</td>
<td>n</td>
</tr>
<tr>
<td>190</td>
<td>1239.5 (1095.5, 1402.5)</td>
<td>170</td>
</tr>
<tr>
<td>170</td>
<td>705.1 (621.4, 800.2)</td>
<td>1.76</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Y</td>
</tr>
</tbody>
</table>

- Noninferiority is declared if the lower bound of the 95% confidence interval is > 0.67
- LBCI for GMR >1 indicating a statistically greater response in 12-15 that 16-25 year olds
## First COVID-19 Occurrence From 7 Days After Dose 2

### Subjects 12-15 Years of Age – Evaluable Efficacy Population

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 µg) N=1005</th>
<th>Placebo N=978</th>
</tr>
</thead>
<tbody>
<tr>
<td>First COVID-19 occurrence ≥7 days after Dose 2</td>
<td>n=0, Surveillance Time (n)=0.154 (1001)</td>
<td>n=16, Surveillance Time (n)=0.147 (972)</td>
</tr>
</tbody>
</table>

- There were no severe COVID-19 cases

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.

The analysis is descriptive; no hypothesis test.
First COVID-19 Occurrence From 7 Days After Dose 2
Subjects 12-15 Years of Age – Evaluable Efficacy Population

Subjects WITH or WITHOUT Evidence of Infection Prior to 7 days after Dose 2

<table>
<thead>
<tr>
<th>Efficacy Endpoint</th>
<th>BNT162b2 (30 µg) N=1119</th>
<th>Placebo N=1110</th>
<th>VE (%)</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First COVID-19 occurrence ≥7 days after Dose 2</td>
<td>0</td>
<td>18</td>
<td>100.0</td>
<td>(78.1, 100.0)</td>
</tr>
</tbody>
</table>

- There were no severe COVID-19 cases

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint. The analysis is descriptive; no hypothesis test
Immunogenicity & Efficacy Conclusions

- Immune response to Pfizer-BioNTech COVID-19 Vaccine in SARS-CoV-2 50% neutralizing titers in adolescents 12-15 years of age was noninferior to (and in fact exceeded) the immune response in young adults 16-25 years of age, which provides immunobridging for adolescents in pivotal Study C4591001.

- In the adolescent group, efficacy analyses based on cases reported from at least 7 days after Dose 2 through the data cutoff date, the observed VE was 100% (95% CI: 75.3%, 100%) for individuals without evidence of prior SARS-CoV-2 infection before and during vaccination regimen, and 100% (2-sided 95% CI: 78.1%, 100%) for those with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen.

- No severe cases were reported in the 12-15 years of age group as of the cutoff date.

- Overall, these immunogenicity and efficacy data strongly support BNT162b2 use in adolescents 12-15 years of age.
Thank you
Questions?