



## Clinical trial results:

### A Phase 2/3 Protocol to Investigate the Safety, Tolerability, and Immunogenicity of BNT162b2 RNA - Based Vaccine Candidates for SARS-Cov-2 New Variants in Healthy Individuals

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2024-000361-24 |
| Trial protocol           | Outside EU/EEA |
| Global end of trial date |                |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1               |
| This version publication date  | 20 December 2024 |
| First version publication date | 20 December 2024 |

#### Trial information

##### Trial identification

|                       |          |
|-----------------------|----------|
| Sponsor protocol code | C4591054 |
|-----------------------|----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT05997290 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                                 |
|------------------------------|-------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | BioNTech SE                                                                                     |
| Sponsor organisation address | An der Goldgrube 12, Mainz, Germany, 55131                                                      |
| Public contact               | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |
| Scientific contact           | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |

Notes:

#### Paediatric regulatory details

|                                                                      |     |
|----------------------------------------------------------------------|-----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No  |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No  |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

|                                                      |               |
|------------------------------------------------------|---------------|
| Analysis stage                                       | Interim       |
| Date of interim/final analysis                       | 25 April 2024 |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 19 March 2024 |
| Global end of trial reached?                         | No            |

Notes:

## General information about the trial

Main objective of the trial:

SSA: Describe the safety & tolerability profile of BNT162b2 (Omi XBB.1.5) 30 micrograms (mcg) in messenger ribonucleic acid (mRNA) coronavirus disease 2019 (COVID-19) vaccine-experienced participants  $\geq 12$  years of age & describe immune response to BNT162b2 (Omi XBB.1.5) 30 mcg & to bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg in mRNA COVID-19 vaccine-experienced participants  $\geq 12$  years of age. SSB: Describe the safety & tolerability profile of BNT162b2 (Omi XBB.1.5) 30 mcg given as a single dose to COVID-19 vaccine-naïve participants who were previously SARS-CoV-2 exposed,  $\geq 12$  years of age & demonstrate the noninferiority with respect to level of neutralizing titer & with respect to seroresponse rate of the anti-XBB.1.5 immune response elicited by BNT162b2 (Omi XBB.1.5) 30 mcg given as a single dose to COVID-19 vaccine-naïve participants, who were previously SARS-CoV-2 exposed,  $\geq 12$  years of age compared to BNT162b2 (Omi XBB.1.5) 30 mcg given to vaccine-experienced participants in SSA.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

|                                                           |                |
|-----------------------------------------------------------|----------------|
| Actual start date of recruitment                          | 10 August 2023 |
| Long term follow-up planned                               | No             |
| Independent data monitoring committee (IDMC) involvement? | Yes            |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 723 |
| Worldwide total number of subjects   | 723                |
| EEA total number of subjects         | 0                  |

Notes:

### Subjects enrolled per age group

|                                           |    |
|-------------------------------------------|----|
| In utero                                  | 0  |
| Preterm newborn - gestational age < 37 wk | 0  |
| Newborns (0-27 days)                      | 0  |
| Infants and toddlers (28 days-23 months)  | 0  |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 39 |

|                      |     |
|----------------------|-----|
| Adults (18-64 years) | 517 |
| From 65 to 84 years  | 165 |
| 85 years and over    | 2   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

SSA: A total of 417 participants were screened in sub-study A out of which 412 were vaccinated. SSB: A total of 311 participants were screened and vaccinated in sub-study B.

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall Study (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Not applicable                 |
| Blinding used                | Not blinded                    |

### Arms

|                              |                           |
|------------------------------|---------------------------|
| Are arms mutually exclusive? | Yes                       |
| <b>Arm title</b>             | SSA: Group 1: 12-17 years |

Arm description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | BNT162b2 (Omi XBB.1.5) |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

|                  |                           |
|------------------|---------------------------|
| <b>Arm title</b> | SSA: Group 2: 18-55 years |
|------------------|---------------------------|

Arm description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | BNT162b2 (Omi XBB.1.5) |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | SSA: Group 3: >55 years |
|------------------|-------------------------|

Arm description:

Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|                                                                                                    |                           |
|----------------------------------------------------------------------------------------------------|---------------------------|
| Investigational medicinal product name                                                             | BNT162b2 (Omi XBB.1.5)    |
| Investigational medicinal product code                                                             |                           |
| Other name                                                                                         |                           |
| Pharmaceutical forms                                                                               | Injection                 |
| Routes of administration                                                                           | Intramuscular use         |
| Dosage and administration details:                                                                 |                           |
| Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly. |                           |
| <b>Arm title</b>                                                                                   | SSB: Group 1: 12-17 years |

Arm description:

Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | BNT162b2 (Omi XBB.1.5) |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

|                  |                           |
|------------------|---------------------------|
| <b>Arm title</b> | SSB: Group 2: 18-55 years |
|------------------|---------------------------|

Arm description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | BNT162b2 (Omi XBB.1.5) |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | SSB: Group 3: >55 years |
|------------------|-------------------------|

Arm description:

Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                                        |                        |
|----------------------------------------|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | BNT162b2 (Omi XBB.1.5) |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Participants received a single dose of 30 mcg BNT162b2 (Omi XBB.1.5) administered intramuscularly.

| Number of subjects in period 1      | SSA: Group 1: 12-17 years | SSA: Group 2: 18-55 years | SSA: Group 3: >55 years |
|-------------------------------------|---------------------------|---------------------------|-------------------------|
| Started                             | 30                        | 174                       | 208                     |
| Safety Population                   | 30                        | 174                       | 208                     |
| Evaluable Immunogenicity Population | 27 <sup>[1]</sup>         | 167 <sup>[2]</sup>        | 188 <sup>[3]</sup>      |
| Completed                           | 29                        | 172                       | 203                     |
| Not completed                       | 1                         | 2                         | 5                       |
| Consent withdrawn by subject        | 1                         | -                         | 2                       |
| Death                               | -                         | -                         | 1                       |
| Lost to follow-up                   | -                         | 2                         | -                       |
| Protocol deviation                  | -                         | -                         | 2                       |

| Number of subjects in period 1      | SSB: Group 1: 12-17 years | SSB: Group 2: 18-55 years | SSB: Group 3: >55 years |
|-------------------------------------|---------------------------|---------------------------|-------------------------|
| Started                             | 9                         | 253                       | 49                      |
| Safety Population                   | 9                         | 253                       | 49                      |
| Evaluable Immunogenicity Population | 9                         | 243                       | 47                      |
| Completed                           | 9                         | 225                       | 44                      |
| Not completed                       | 0                         | 28                        | 5                       |
| Consent withdrawn by subject        | -                         | 6                         | 1                       |
| Death                               | -                         | -                         | -                       |
| Lost to follow-up                   | -                         | 22                        | 4                       |
| Protocol deviation                  | -                         | -                         | -                       |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

## Baseline characteristics

### Reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                                          |                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSA: Group 1: 12-17 years |
| Reporting group description:<br>Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study. |                           |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSA: Group 2: 18-55 years |
| Reporting group description:<br>Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                 |                           |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSA: Group 3: >55 years   |
| Reporting group description:<br>Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.      |                           |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSB: Group 1: 12-17 years |
| Reporting group description:<br>Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                   |                           |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSB: Group 2: 18-55 years |
| Reporting group description:<br>Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                                                                     |                           |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                    | SSB: Group 3: >55 years   |
| Reporting group description:<br>Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                                                                       |                           |

| Reporting group values    | SSA: Group 1: 12-17 years | SSA: Group 2: 18-55 years | SSA: Group 3: >55 years |
|---------------------------|---------------------------|---------------------------|-------------------------|
| Number of subjects        | 30                        | 174                       | 208                     |
| Age Categorical           |                           |                           |                         |
| Units: Participants       |                           |                           |                         |
| Adolescents (12-17 years) | 30                        | 0                         | 0                       |
| Adults (18-64 years)      | 0                         | 174                       | 63                      |
| From 65-84 years          | 0                         | 0                         | 143                     |
| 85 years and over         | 0                         | 0                         | 2                       |
| Age Continuous            |                           |                           |                         |
| Units: years              |                           |                           |                         |
| arithmetic mean           | 14.0                      | 40.4                      | 68.6                    |
| standard deviation        | ± 1.74                    | ± 9.82                    | ± 6.74                  |
| Gender Categorical        |                           |                           |                         |
| Units: Participants       |                           |                           |                         |
| Female                    | 19                        | 100                       | 123                     |
| Male                      | 11                        | 74                        | 85                      |

|                                           |    |     |     |
|-------------------------------------------|----|-----|-----|
| Race                                      |    |     |     |
| Units: Subjects                           |    |     |     |
| White                                     | 26 | 135 | 164 |
| Black or African American                 | 3  | 23  | 27  |
| American Indian or Alaska Native          | 0  | 0   | 1   |
| Asian                                     | 1  | 11  | 10  |
| Native Hawaiian or other Pacific Islander | 0  | 0   | 2   |
| Multiracial                               | 0  | 5   | 3   |
| Unknown                                   | 0  | 0   | 1   |
| Ethnicity                                 |    |     |     |
| Units: Subjects                           |    |     |     |
| Hispanic/Latino                           | 6  | 35  | 34  |
| Non-Hispanic/non-Latino                   | 24 | 138 | 173 |
| Not reported                              | 0  | 1   | 1   |

| Reporting group values                    | SSB: Group 1: 12-17 years | SSB: Group 2: 18-55 years | SSB: Group 3: >55 years |
|-------------------------------------------|---------------------------|---------------------------|-------------------------|
| Number of subjects                        | 9                         | 253                       | 49                      |
| Age Categorical                           |                           |                           |                         |
| Units: Participants                       |                           |                           |                         |
| Adolescents (12-17 years)                 | 9                         | 0                         | 0                       |
| Adults (18-64 years)                      | 0                         | 253                       | 27                      |
| From 65-84 years                          | 0                         | 0                         | 22                      |
| 85 years and over                         | 0                         | 0                         | 0                       |
| Age Continuous                            |                           |                           |                         |
| Units: years                              |                           |                           |                         |
| arithmetic mean                           | 14.6                      | 34.5                      | 64.0                    |
| standard deviation                        | ± 1.67                    | ± 10.43                   | ± 6.35                  |
| Gender Categorical                        |                           |                           |                         |
| Units: Participants                       |                           |                           |                         |
| Female                                    | 5                         | 138                       | 23                      |
| Male                                      | 4                         | 115                       | 26                      |
| Race                                      |                           |                           |                         |
| Units: Subjects                           |                           |                           |                         |
| White                                     | 2                         | 162                       | 30                      |
| Black or African American                 | 7                         | 87                        | 16                      |
| American Indian or Alaska Native          | 0                         | 0                         | 1                       |
| Asian                                     | 0                         | 4                         | 2                       |
| Native Hawaiian or other Pacific Islander | 0                         | 0                         | 0                       |
| Multiracial                               | 0                         | 0                         | 0                       |
| Unknown                                   | 0                         | 0                         | 0                       |
| Ethnicity                                 |                           |                           |                         |
| Units: Subjects                           |                           |                           |                         |
| Hispanic/Latino                           | 3                         | 136                       | 19                      |
| Non-Hispanic/non-Latino                   | 6                         | 117                       | 30                      |
| Not reported                              | 0                         | 0                         | 0                       |

| Reporting group values | Total |  |  |
|------------------------|-------|--|--|
| Number of subjects     | 723   |  |  |



|                                           |     |  |  |
|-------------------------------------------|-----|--|--|
| Age Categorical                           |     |  |  |
| Units: Participants                       |     |  |  |
| Adolescents (12-17 years)                 | 39  |  |  |
| Adults (18-64 years)                      | 517 |  |  |
| From 65-84 years                          | 165 |  |  |
| 85 years and over                         | 2   |  |  |
| Age Continuous                            |     |  |  |
| Units: years                              |     |  |  |
| arithmetic mean                           |     |  |  |
| standard deviation                        | -   |  |  |
| Gender Categorical                        |     |  |  |
| Units: Participants                       |     |  |  |
| Female                                    | 408 |  |  |
| Male                                      | 315 |  |  |
| Race                                      |     |  |  |
| Units: Subjects                           |     |  |  |
| White                                     | 519 |  |  |
| Black or African American                 | 163 |  |  |
| American Indian or Alaska Native          | 2   |  |  |
| Asian                                     | 28  |  |  |
| Native Hawaiian or other Pacific Islander | 2   |  |  |
| Multiracial                               | 8   |  |  |
| Unknown                                   | 1   |  |  |
| Ethnicity                                 |     |  |  |
| Units: Subjects                           |     |  |  |
| Hispanic/Latino                           | 233 |  |  |
| Non-Hispanic/non-Latino                   | 488 |  |  |
| Not reported                              | 2   |  |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSA: Group 1: 12-17 years                             |
| Reporting group description:<br>Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via intramuscular (IM) route on Day 1 of this study.                    |                                                       |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSA: Group 2: 18-55 years                             |
| Reporting group description:<br>Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                    |                                                       |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSA: Group 3: >55 years                               |
| Reporting group description:<br>Participants aged greater than (>) 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                         |                                                       |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSB: Group 1: 12-17 years                             |
| Reporting group description:<br>Participants aged 12-17 years who were previously exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                                      |                                                       |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSB: Group 2: 18-55 years                             |
| Reporting group description:<br>Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                                                                                        |                                                       |
| Reporting group title                                                                                                                                                                                                                                                                                                                                                                                                       | SSB: Group 3: >55 years                               |
| Reporting group description:<br>Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.                                                                                                                                                                                          |                                                       |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                  | SSA Total Study Participants: C4591054                |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                   | Safety analysis                                       |
| Subject analysis set description:<br>Participants who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for safety analysis. |                                                       |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                  | SSA Historical Control: C4591044 BNT162b2 12-17 years |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                          |
| Subject analysis set description:<br>Participants aged 12 to 17 years from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.                                                                                                           |                                                       |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                  | SSA Historical Control: C4591044 BNT162b2 18-55 years |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                          |
| Subject analysis set description:<br>Participants aged 18 to 55 years from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.                                                                                                           |                                                       |
| Subject analysis set title                                                                                                                                                                                                                                                                                                                                                                                                  | SSA Historical Control: C4591044 BNT162b2 >55 years   |
| Subject analysis set type                                                                                                                                                                                                                                                                                                                                                                                                   | Per protocol                                          |

**Subject analysis set description:**

Participants aged >55 years from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.

|                            |                                        |
|----------------------------|----------------------------------------|
| Subject analysis set title | SSA Total Study Participants: C4591054 |
| Subject analysis set type  | Per protocol                           |

**Subject analysis set description:**

Participants who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study. This analysis set is created for immunogenicity analysis.

|                            |                                                 |
|----------------------------|-------------------------------------------------|
| Subject analysis set title | SSA Total Historical Control: C4591044 BNT162b2 |
| Subject analysis set type  | Per protocol                                    |

**Subject analysis set description:**

Participants from study C4591044 (NCT05472038) Cohort 2/Cohort 3 who received bivalent BNT162b2 (WT/Omi BA.4/BA.5) 30 mcg as a fourth dose were used as historical control for immunogenicity. This analysis set is created for immunogenicity analysis.

|                            |                              |
|----------------------------|------------------------------|
| Subject analysis set title | SSB Total Study Participants |
| Subject analysis set type  | Safety analysis              |

**Subject analysis set description:**

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for safety analysis.

|                            |                               |
|----------------------------|-------------------------------|
| Subject analysis set title | SSB: Vaccine-Naïve Substudy B |
| Subject analysis set type  | Per protocol                  |

**Subject analysis set description:**

Participants aged >=12 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSB. This analysis set is created for immunogenicity analysis.

|                            |                                             |
|----------------------------|---------------------------------------------|
| Subject analysis set title | SSB Control: Vaccine-Experienced Substudy A |
| Subject analysis set type  | Per protocol                                |

**Subject analysis set description:**

Participants who received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 in SSA were included. This analysis set is created for immunogenicity analysis.

## **Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSA**

|                 |                                                                                                        |
|-----------------|--------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSA <sup>[1][2]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------|

**End point description:**

Local reactions: pain at injection site, redness and swelling recorded by participants in an electronic diary (e-diary) or as adverse events (AEs) in the case report form (CRF). Redness & swelling measured & recorded in measuring device units (mdu)(range:1 to 21),1mdu=0.5 cm &were graded as mild (greater than[>] 2.0 to 5.0 cm),moderate(>5.0 to 10.0 cm),severe(>10.0 cm)&Grade 4(necrosis [swelling]&necrosis or exfoliative dermatitis[redness]).Pain at injection site graded as mild(did not interfere with activity),moderate(interfered with activity),severe(prevented daily activity)&Grade(G)4(emergency room [ER]visit or hospitalisation for severe pain at injection site).G4 LR classified by investigator or medically qualified person.Exact 2-sided confidence interval(CI)based on Clopper and Pearson method. Safety population: all participants who received study intervention.Number of Participants Analysed=Participants evaluable.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

**End point timeframe:**

Day 1 to Day 7 after vaccination

**Notes:**

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the

baseline period arms will be reported on when providing values for an end point on the baseline period.  
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                     | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Total<br>Study<br>Participants:<br>C4591054 |
|--------------------------------------|------------------------------|------------------------------|----------------------------|-------------------------------------------------|
| Subject group type                   | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                            |
| Number of subjects analysed          | 30                           | 174                          | 206                        | 410                                             |
| Units: Percentage of Participants    |                              |                              |                            |                                                 |
| number (confidence interval 95%)     |                              |                              |                            |                                                 |
| Redness: Any                         | 10.0 (2.1 to 26.5)           | 4.0 (1.6 to 8.1)             | 5.8 (3.0 to 10.0)          | 5.4 (3.4 to 8.0)                                |
| Redness: Mild                        | 6.7 (0.8 to 22.1)            | 3.4 (1.3 to 7.4)             | 3.9 (1.7 to 7.5)           | 3.9 (2.2 to 6.3)                                |
| Redness: Moderate                    | 3.3 (0.1 to 17.2)            | 0.6 (0.0 to 3.2)             | 1.9 (0.5 to 4.9)           | 1.5 (0.5 to 3.2)                                |
| Redness: Severe                      | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Redness: Grade 4                     | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Swelling: Any                        | 16.7 (5.6 to 34.7)           | 7.5 (4.0 to 12.4)            | 5.8 (3.0 to 10.0)          | 7.3 (5.0 to 10.3)                               |
| Swelling: Mild                       | 13.3 (3.8 to 30.7)           | 5.7 (2.8 to 10.3)            | 3.9 (1.7 to 7.5)           | 5.4 (3.4 to 8.0)                                |
| Swelling: Moderate                   | 3.3 (0.1 to 17.2)            | 1.7 (0.4 to 5.0)             | 1.9 (0.5 to 4.9)           | 2.0 (0.8 to 3.8)                                |
| Swelling: Severe                     | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Swelling: Grade 4                    | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Pain at the injection site: Any      | 80.0 (61.4 to 92.3)          | 75.9 (68.8 to 82.0)          | 52.4 (45.4 to 59.4)        | 64.4 (59.5 to 69.0)                             |
| Pain at the injection site: Mild     | 50.0 (31.3 to 68.7)          | 59.8 (52.1 to 67.1)          | 46.6 (39.6 to 53.7)        | 52.4 (47.5 to 57.4)                             |
| Pain at the injection site: Moderate | 30.0 (14.7 to 49.4)          | 16.1 (11.0 to 22.4)          | 5.8 (3.0 to 10.0)          | 12.0 (9.0 to 15.5)                              |
| Pain at the injection site: Severe   | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Pain at the injection site: Grade 4  | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSA

|                 |                                                                                                                    |
|-----------------|--------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSA <sup>[3]</sup> <sup>[4]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature  $\geq 38$  degree Celsius (deg C) and categorised as  $\geq 38.0$ -38.4 deg C,  $>38.4$ -38.9 deg C,  $>38.9$ -40.0 deg C and  $>40.0$  deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24 hours (h), moderate:  $>2$  times in 24h, severe: required intravenous (IV) hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention. Number of Participants Analysed= Participants evaluable.

|                                  |         |
|----------------------------------|---------|
| End point type                   | Primary |
| End point timeframe:             |         |
| Day 1 to Day 7 after vaccination |         |

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                        | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Total<br>Study<br>Participants:<br>C4591054 |
|-----------------------------------------|------------------------------|------------------------------|----------------------------|-------------------------------------------------|
| Subject group type                      | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                            |
| Number of subjects analysed             | 30                           | 174                          | 206                        | 410                                             |
| Units: Percentage of participants       |                              |                              |                            |                                                 |
| number (confidence interval 95%)        |                              |                              |                            |                                                 |
| Fever: Any                              | 16.7 (5.6 to 34.7)           | 4.0 (1.6 to 8.1)             | 3.9 (1.7 to 7.5)           | 4.9 (3.0 to 7.4)                                |
| Fever: >=38.0 degree C to 38.4 degree C | 10.0 (2.1 to 26.5)           | 3.4 (1.3 to 7.4)             | 2.4 (0.8 to 5.6)           | 3.4 (1.9 to 5.7)                                |
| Fever: >38.4 degree C to 38.9 degree C  | 3.3 (0.1 to 17.2)            | 0.6 (0.0 to 3.2)             | 1.0 (0.1 to 3.5)           | 1.0 (0.3 to 2.5)                                |
| Fever: >38.9 degree C to 40.0 degree C  | 3.3 (0.1 to 17.2)            | 0 (0.0 to 2.1)               | 0.5 (0.0 to 2.7)           | 0.5 (0.1 to 1.8)                                |
| Fever: >40.0 degree C                   | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Fatigue: Any                            | 56.7 (37.4 to 74.5)          | 56.9 (49.2 to 64.4)          | 35.4 (28.9 to 42.4)        | 46.1 (41.2 to 51.1)                             |
| Fatigue: Mild                           | 30.0 (14.7 to 49.4)          | 31.6 (24.8 to 39.1)          | 18.4 (13.4 to 24.4)        | 24.9 (20.8 to 29.4)                             |
| Fatigue: Moderate                       | 26.7 (12.3 to 45.9)          | 24.1 (18.0 to 31.2)          | 17.0 (12.1 to 22.8)        | 20.7 (16.9 to 25.0)                             |
| Fatigue: Severe                         | 0 (0.0 to 11.6)              | 1.1 (0.1 to 4.1)             | 0 (0.0 to 1.8)             | 0.5 (0.1 to 1.8)                                |
| Fatigue: Grade 4                        | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Headache: Any                           | 36.7 (19.9 to 56.1)          | 43.7 (36.2 to 51.4)          | 26.2 (20.3 to 32.8)        | 34.4 (29.8 to 39.2)                             |
| Headache: Mild                          | 30.0 (14.7 to 49.4)          | 31.0 (24.3 to 38.5)          | 20.4 (15.1 to 26.5)        | 25.6 (21.5 to 30.1)                             |
| Headache: Moderate                      | 6.7 (0.8 to 22.1)            | 12.6 (8.1 to 18.5)           | 5.8 (3.0 to 10.0)          | 8.8 (6.2 to 11.9)                               |
| Headache: Severe                        | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Headache: Grade 4                       | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Chills: Any                             | 20.0 (7.7 to 38.6)           | 9.2 (5.3 to 14.5)            | 9.2 (5.6 to 14.0)          | 10.0 (7.3 to 13.3)                              |
| Chills: Mild                            | 10.0 (2.1 to 26.5)           | 6.9 (3.6 to 11.7)            | 6.3 (3.4 to 10.5)          | 6.8 (4.6 to 9.7)                                |
| Chills: Moderate                        | 10.0 (2.1 to 26.5)           | 2.3 (0.6 to 5.8)             | 2.9 (1.1 to 6.2)           | 3.2 (1.7 to 5.4)                                |
| Chills: Severe                          | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Chills: Grade 4                         | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Vomiting: Any                           | 0 (0.0 to 11.6)              | 2.3 (0.6 to 5.8)             | 0 (0.0 to 1.8)             | 1.0 (0.3 to 2.5)                                |
| Vomiting: Mild                          | 0 (0.0 to 11.6)              | 2.3 (0.6 to 5.8)             | 0 (0.0 to 1.8)             | 1.0 (0.3 to 2.5)                                |
| Vomiting: Moderate                      | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Vomiting: Severe                        | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |
| Vomiting: Grade 4                       | 0 (0.0 to 11.6)              | 0 (0.0 to 2.1)               | 0 (0.0 to 1.8)             | 0 (0.0 to 0.9)                                  |

|                                       |                    |                     |                    |                     |
|---------------------------------------|--------------------|---------------------|--------------------|---------------------|
| Diarrhea: Any                         | 0 (0.0 to 11.6)    | 13.2 (8.6 to 19.2)  | 8.7 (5.3 to 13.5)  | 10.0 (7.3 to 13.3)  |
| Diarrhea: Mild                        | 0 (0.0 to 11.6)    | 11.5 (7.2 to 17.2)  | 7.3 (4.1 to 11.7)  | 8.5 (6.0 to 11.7)   |
| Diarrhea: Moderate                    | 0 (0.0 to 11.6)    | 1.1 (0.1 to 4.1)    | 1.5 (0.3 to 4.2)   | 1.2 (0.4 to 2.8)    |
| Diarrhea: Severe                      | 0 (0.0 to 11.6)    | 0.6 (0.0 to 3.2)    | 0 (0.0 to 1.8)     | 0.2 (0.0 to 1.4)    |
| Diarrhea: Grade 4                     | 0 (0.0 to 11.6)    | 0 (0.0 to 2.1)      | 0 (0.0 to 1.8)     | 0 (0.0 to 0.9)      |
| New or worsened muscle pain: Any      | 23.3 (9.9 to 42.3) | 21.8 (15.9 to 28.7) | 12.1 (8.0 to 17.4) | 17.1 (13.6 to 21.1) |
| New or worsened muscle pain: Mild     | 3.3 (0.1 to 17.2)  | 12.1 (7.6 to 17.9)  | 5.3 (2.7 to 9.4)   | 8.0 (5.6 to 11.1)   |
| New or worsened muscle pain: Moderate | 20.0 (7.7 to 38.6) | 9.8 (5.8 to 15.2)   | 6.8 (3.8 to 11.1)  | 9.0 (6.4 to 12.2)   |
| New or worsened muscle pain: Severe   | 0 (0.0 to 11.6)    | 0 (0.0 to 2.1)      | 0 (0.0 to 1.8)     | 0 (0.0 to 0.9)      |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 11.6)    | 0 (0.0 to 2.1)      | 0 (0.0 to 1.8)     | 0 (0.0 to 0.9)      |
| New or worsened joint pain: Any       | 16.7 (5.6 to 34.7) | 14.4 (9.5 to 20.5)  | 7.8 (4.5 to 12.3)  | 11.2 (8.3 to 14.7)  |
| New or worsened joint pain: Mild      | 6.7 (0.8 to 22.1)  | 8.6 (4.9 to 13.8)   | 5.3 (2.7 to 9.4)   | 6.8 (4.6 to 9.7)    |
| New or worsened joint pain: Moderate  | 10.0 (2.1 to 26.5) | 5.7 (2.8 to 10.3)   | 2.4 (0.8 to 5.6)   | 4.4 (2.6 to 6.8)    |
| New or worsened joint pain: Severe    | 0 (0.0 to 11.6)    | 0 (0.0 to 2.1)      | 0 (0.0 to 1.8)     | 0 (0.0 to 0.9)      |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 11.6)    | 0 (0.0 to 2.1)      | 0 (0.0 to 1.8)     | 0 (0.0 to 0.9)      |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Adverse Events (AEs) From Vaccination Through 1 Month After Vaccination: SSA

|                 |                                                                                                                                            |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Adverse Events (AEs) From Vaccination Through 1 Month After Vaccination: SSA <sup>[5]</sup> <sup>[6]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received the study intervention.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Total<br>Study<br>Participants:<br>C4591054 |
|-----------------------------------|------------------------------|------------------------------|----------------------------|-------------------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                            |
| Number of subjects analysed       | 30                           | 174                          | 208                        | 412                                             |
| Units: Percentage of participants |                              |                              |                            |                                                 |
| number (confidence interval 95%)  | 16.7 (5.6 to 34.7)           | 7.5 (4.0 to 12.4)            | 8.2 (4.8 to 12.8)          | 8.5 (6.0 to 11.6)                               |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Serious Adverse Events (SAEs) From Vaccination Through 6 Months After the Study Vaccination: SSA

|                 |                                                                                                                                                                |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Serious Adverse Events (SAEs) From Vaccination Through 6 Months After the Study Vaccination: SSA <sup>[7]</sup> <sup>[8]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Safety population included all participants who received the study intervention.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Total<br>Study<br>Participants:<br>C4591054 |
|-----------------------------------|------------------------------|------------------------------|----------------------------|-------------------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                            |
| Number of subjects analysed       | 30                           | 174                          | 208                        | 412                                             |
| Units: Percentage of Participants |                              |                              |                            |                                                 |
| number (confidence interval 95%)  | 3.3 (0.1 to 17.2)            | 0 (0.0 to 2.1)               | 1.9 (0.5 to 4.9)           | 1.2 (0.4 to 2.8)                                |

## Statistical analyses

No statistical analyses for this end point

**Primary: Geometric Mean Titers (GMT) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044**

|                 |                                                                                                                                                                                                                                                                                           |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Titers (GMT) of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[9]</sup> <sup>[10]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the lower limit of quantitation (LLOQ) were set to 0.5\*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 1 month after vaccination

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|------------------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                       | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed              | 27                           | 166                          | 185                        | 15                                                                 |
| Units: Titer                             |                              |                              |                            |                                                                    |
| geometric mean (confidence interval 95%) | 3632.1 (2043.8 to 6454.7)    | 2503.6 (2003.0 to 3129.3)    | 2606.8 (2065.5 to 3289.9)  | 837.1 (459.5 to 1524.9)                                            |

| End point values                         | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                       | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed              | 85                                                                 | 100                                                             | 378                                             | 200                                                         |
| Units: Titer                             |                                                                    |                                                                 |                                                 |                                                             |
| geometric mean (confidence interval 95%) | 615.5 (459.0 to 825.2)                                             | 560.4 (430.0 to 730.2)                                          | 2622.3 (2246.6 to 3060.9)                       | 601.0 (499.5 to 723.1)                                      |

**Statistical analyses**



**Primary: GMT of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044**

|                 |                                                                                                                                                                                                                    |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMT of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[11]</sup> <sup>[12]</sup> |
|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5\*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 1 month after vaccination

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                         | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|------------------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                       | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed              | 26                           | 167                          | 187                        | 15                                                                 |
| Units: Titer                             |                              |                              |                            |                                                                    |
| geometric mean (confidence interval 95%) | 7903.6 (4961.5 to 12590.4)   | 4831.8 (4044.5 to 5772.3)    | 5046.1 (4123.3 to 6175.3)  | 6376.3 (3568.4 to 11393.8)                                         |

| End point values                         | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                       | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed              | 85                                                                 | 100                                                             | 380                                             | 200                                                         |
| Units: Titer                             |                                                                    |                                                                 |                                                 |                                                             |
| geometric mean (confidence interval 95%) | 3868.2 (2974.8 to 5029.9)                                          | 4122.7 (3261.2 to 5211.6)                                       | 5105.1 (4483.4 to 5813.0)                       | 4146.0 (3512.6 to 4893.5)                                   |

## Statistical analyses

No statistical analyses for this end point

### Primary: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

|                 |                                                                                                                                                                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[13]</sup> <sup>[14]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

GMFR and 2-sided 95% CI were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5\*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

#### End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

#### Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                            | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|---------------------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                          | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed                 | 27                           | 165                          | 184                        | 15                                                                 |
| Units: Fold rise                            |                              |                              |                            |                                                                    |
| geometric mean (confidence interval<br>95%) | 11.8 (6.3 to<br>22.2)        | 10.7 (8.7 to<br>13.1)        | 13.5 (10.7 to<br>17.1)     | 7.1 (3.9 to<br>12.8)                                               |

| End point values                            | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|---------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                          | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed                 | 82                                                                 | 100                                                             | 376                                             | 197                                                         |
| Units: Fold rise                            |                                                                    |                                                                 |                                                 |                                                             |
| geometric mean (confidence interval<br>95%) | 6.1 (4.5 to 8.3)                                                   | 5.2 (4.1 to 6.5)                                                | 12.1 (10.4 to<br>14.0)                          | 5.7 (4.8 to 6.8)                                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: GMFR of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

|                 |                                                                                                                                                                                                                                 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | GMFR of SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers From Before Vaccination to 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[15][16]</sup> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

GMFR and 2-sided 95% CI were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5\*LLOQ. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

#### End point timeframe:

From before vaccination on Day 1 up to 1 month after vaccination

#### Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                            | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|---------------------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                          | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed                 | 26                           | 167                          | 186                        | 15                                                                 |
| Units: Fold rise                            |                              |                              |                            |                                                                    |
| geometric mean (confidence interval<br>95%) | 3.5 (2.2 to 5.8)             | 4.3 (3.7 to 5.0)             | 5.1 (4.3 to 6.2)           | 5.7 (3.4 to 9.4)                                                   |

| End point values                            | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|---------------------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                          | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed                 | 85                                                                 | 100                                                             | 379                                             | 200                                                         |
| Units: Fold rise                            |                                                                    |                                                                 |                                                 |                                                             |
| geometric mean (confidence interval<br>95%) | 6.2 (4.6 to 8.4)                                                   | 7.4 (5.7 to 9.6)                                                | 4.6 (4.1 to 5.2)                                | 6.8 (5.6 to 8.1)                                            |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

|                 |                                                                                                                                                                                                                                               |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Seroresponse to SARS-CoV-2 Omi XBB.1.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[17][18]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Seroresponse was defined as achieving  $\geq 4$ -fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination assay result of  $\geq 4 \times$  LLOQ was considered a seroresponse. Exact 2-sided CI was based on the Clopper and Pearson method. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 1 month after vaccination

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|-----------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed       | 27                           | 165                          | 184                        | 15                                                                 |
| Units: Percentage of Participants |                              |                              |                            |                                                                    |
| number (confidence interval 95%)  | 74.1 (53.7 to<br>88.9)       | 76.4 (69.1 to<br>82.6)       | 71.7 (64.6 to<br>78.1)     | 66.7 (38.4 to<br>88.2)                                             |

| End point values                  | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|-----------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed       | 82                                                                 | 100                                                             | 376                                             | 197                                                         |
| Units: Percentage of Participants |                                                                    |                                                                 |                                                 |                                                             |
| number (confidence interval 95%)  | 52.4 (41.1 to<br>63.6)                                             | 51.0 (40.8 to<br>61.1)                                          | 73.9 (69.2 to<br>78.3)                          | 52.8 (45.6 to<br>59.9)                                      |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Seroresponse to SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044

|                 |                                                                                                                                                                                                                                                             |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Seroresponse to SARS-CoV-2 Omi BA.4/BA.5-Neutralizing Titers at 1 Month After Vaccination: SSA and Historical Control of the Bivalent BNT162b2 (WT/Omi BA.4/BA.5) Group from Study C4591044 <sup>[19]</sup> <sup>[20]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Seroresponse was defined as achieving  $\geq 4$ -fold rise from baseline (before the study vaccination). If the baseline measurement was below the LLOQ, the postvaccination assay result of  $\geq 4 \times$  LLOQ was considered a seroresponse. Exact 2-sided CI was based on the Clopper and Pearson method. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

#### End point timeframe:

At 1 month after vaccination

#### Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSA: Group 1:<br>12-17 years | SSA: Group 2:<br>18-55 years | SSA: Group 3:<br>>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 12-<br>17 years |
|-----------------------------------|------------------------------|------------------------------|----------------------------|--------------------------------------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set                                               |
| Number of subjects analysed       | 26                           | 167                          | 186                        | 15                                                                 |
| Units: Percentage of participants |                              |                              |                            |                                                                    |
| number (confidence interval 95%)  | 46.2 (26.6 to<br>66.6)       | 43.7 (36.1 to<br>51.6)       | 52.7 (45.3 to<br>60.0)     | 73.3 (44.9 to<br>92.2)                                             |

| End point values                  | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 18-<br>55 years | SSA Historical<br>Control:<br>C4591044<br>BNT162b2 >55<br>years | SSA Total<br>Study<br>Participants:<br>C4591054 | SSA Total<br>Historical<br>Control:<br>C4591044<br>BNT162b2 |
|-----------------------------------|--------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------------------|
| Subject group type                | Subject analysis set                                               | Subject analysis set                                            | Subject analysis set                            | Subject analysis set                                        |
| Number of subjects analysed       | 85                                                                 | 100                                                             | 379                                             | 200                                                         |
| Units: Percentage of participants |                                                                    |                                                                 |                                                 |                                                             |
| number (confidence interval 95%)  | 58.8 (47.6 to<br>69.4)                                             | 65.0 (54.8 to<br>74.3)                                          | 48.3 (43.2 to<br>53.4)                          | 63.0 (55.9 to<br>69.7)                                      |

## Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSB

|                 |                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Local Reactions Within 7 Days After Vaccination: SSB <sup>[21][22]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------|

End point description:

Local reactions: pain at injection site, redness and swelling recorded by participants in an e-diary or as AEs in the CRF. Redness & swelling measured & recorded in mdu (range:1 to 21), 1 mdu= 0.5 cm & were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) & Grade 4 (necrosis [swelling] & necrosis or exfoliative dermatitis [redness]). Pain at injection site graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) & G4 (ER visit or hospitalisation for severe pain at injection site). G4 LR classified by investigator or medically qualified person. Exact 2-sided CI based on Clopper and Pearson method. Safety population: all participants who received study intervention. Number of Participants Analysed= Participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSB: Group 1:<br>12-17 years | SSB: Group 2:<br>18-55 years | SSB: Group 3:<br>>55 years | SSB Total<br>Study<br>Participants |
|-----------------------------------|------------------------------|------------------------------|----------------------------|------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set               |
| Number of subjects analysed       | 9                            | 250                          | 49                         | 308                                |
| Units: Percentage of Participants |                              |                              |                            |                                    |
| number (confidence interval 95%)  |                              |                              |                            |                                    |
| Redness: Any                      | 0 (0.0 to 33.6)              | 8.8 (5.6 to 13.0)            | 2.0 (0.1 to 10.9)          | 7.5 (4.8 to 11.0)                  |
| Redness: Mild                     | 0 (0.0 to 33.6)              | 5.6 (3.1 to 9.2)             | 2.0 (0.1 to 10.9)          | 4.9 (2.8 to 7.9)                   |
| Redness: Moderate                 | 0 (0.0 to 33.6)              | 2.8 (1.1 to 5.7)             | 0 (0.0 to 7.3)             | 2.3 (0.9 to 4.6)                   |
| Redness: Severe                   | 0 (0.0 to 33.6)              | 0.4 (0.0 to 2.2)             | 0 (0.0 to 7.3)             | 0.3 (0.0 to 1.8)                   |
| Redness: Grade 4                  | 0 (0.0 to 33.6)              | 0 (0.0 to 1.5)               | 0 (0.0 to 7.3)             | 0 (0.0 to 1.2)                     |
| Swelling: Any                     | 11.1 (0.3 to 48.2)           | 12.0 (8.2 to 16.7)           | 10.2 (3.4 to 22.2)         | 11.7 (8.3 to 15.8)                 |
| Swelling: Mild                    | 11.1 (0.3 to 48.2)           | 6.8 (4.0 to 10.7)            | 8.2 (2.3 to 19.6)          | 7.1 (4.5 to 10.6)                  |
| Swelling: Moderate                | 0 (0.0 to 33.6)              | 5.2 (2.8 to 8.7)             | 2.0 (0.1 to 10.9)          | 4.5 (2.5 to 7.5)                   |
| Swelling: Severe                  | 0 (0.0 to 33.6)              | 0 (0.0 to 1.5)               | 0 (0.0 to 7.3)             | 0 (0.0 to 1.2)                     |

|                                      |                     |                     |                     |                     |
|--------------------------------------|---------------------|---------------------|---------------------|---------------------|
| Swelling: Grade 4                    | 0 (0.0 to 33.6)     | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Pain at the injection site: Any      | 44.4 (13.7 to 78.8) | 58.0 (51.6 to 64.2) | 36.7 (23.4 to 51.7) | 54.2 (48.5 to 59.9) |
| Pain at the injection site: Mild     | 44.4 (13.7 to 78.8) | 36.4 (30.4 to 42.7) | 32.7 (19.9 to 47.5) | 36.0 (30.7 to 41.7) |
| Pain at the injection site: Moderate | 0 (0.0 to 33.6)     | 21.2 (16.3 to 26.8) | 4.1 (0.5 to 14.0)   | 17.9 (13.7 to 22.6) |
| Pain at the injection site: Severe   | 0 (0.0 to 33.6)     | 0.4 (0.0 to 2.2)    | 0 (0.0 to 7.3)      | 0.3 (0.0 to 1.8)    |
| Pain at the injection site: Grade 4  | 0 (0.0 to 33.6)     | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSB

|                 |                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With Systemic Events Within 7 Days After Vaccination: SSB <sup>[23]</sup> <sup>[24]</sup> |
|-----------------|----------------------------------------------------------------------------------------------------------------------|

End point description:

Systemic events were recorded by participants in an e-diary or as AEs in the CRF. Fever: defined as oral temperature  $\geq 38$  deg C and categorised as  $\geq 38.0$ -38.4 deg C,  $>38.4$ -38.9 deg C,  $>38.9$ -40.0 deg C and  $>40.0$  deg C. Fatigue, headache, chills, new or worsened muscle pain and joint pain: mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily routine activity). Vomiting: mild: 1-2 times in 24h, moderate:  $>2$  times in 24h, severe: required IV hydration. Diarrhoea: mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h, severe: 6 or more loose stools in 24h. Grade 4 for all events except fever: ER visit/hospitalization. Grade 4 events were classified by investigator or medically qualified person. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: All participants who received the study intervention. Number of Participants Analysed= Participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Day 1 to Day 7 after vaccination

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                             | SSB: Group 1:<br>12-17 years | SSB: Group 2:<br>18-55 years | SSB: Group 3:<br>>55 years | SSB Total<br>Study<br>Participants |
|----------------------------------------------|------------------------------|------------------------------|----------------------------|------------------------------------|
| Subject group type                           | Reporting group              | Reporting group              | Reporting group            | Subject analysis set               |
| Number of subjects analysed                  | 9                            | 250                          | 49                         | 308                                |
| Units: Percentage of participants            |                              |                              |                            |                                    |
| number (confidence interval 95%)             |                              |                              |                            |                                    |
| Fever: Any                                   | 11.1 (0.3 to 48.2)           | 2.4 (0.9 to 5.2)             | 6.1 (1.3 to 16.9)          | 3.2 (1.6 to 5.9)                   |
| Fever: $\geq 38.0$ degree C to 38.4 degree C | 0 (0.0 to 33.6)              | 0.8 (0.1 to 2.9)             | 4.1 (0.5 to 14.0)          | 1.3 (0.4 to 3.3)                   |
| Fever: $>38.4$ degree C to 38.9 degree C     | 11.1 (0.3 to 48.2)           | 1.2 (0.2 to 3.5)             | 0 (0.0 to 7.3)             | 1.3 (0.4 to 3.3)                   |
| Fever: $>38.9$ degree C to 40.0 degree C     | 0 (0.0 to 33.6)              | 0.4 (0.0 to 2.2)             | 2.0 (0.1 to 10.9)          | 0.6 (0.1 to 2.3)                   |

|                                       |                    |                     |                     |                     |
|---------------------------------------|--------------------|---------------------|---------------------|---------------------|
| Fever: >40.0 degree C                 | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Fatigue: Any                          | 11.1 (0.3 to 48.2) | 34.8 (28.9 to 41.1) | 24.5 (13.3 to 38.9) | 32.5 (27.3 to 38.0) |
| Fatigue: Mild                         | 0 (0.0 to 33.6)    | 13.6 (9.6 to 18.5)  | 8.2 (2.3 to 19.6)   | 12.3 (8.9 to 16.5)  |
| Fatigue: Moderate                     | 11.1 (0.3 to 48.2) | 21.2 (16.3 to 26.8) | 16.3 (7.3 to 29.7)  | 20.1 (15.8 to 25.0) |
| Fatigue: Severe                       | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Fatigue: Grade 4                      | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Headache: Any                         | 11.1 (0.3 to 48.2) | 30.8 (25.1 to 36.9) | 16.3 (7.3 to 29.7)  | 27.9 (23.0 to 33.3) |
| Headache: Mild                        | 11.1 (0.3 to 48.2) | 12.0 (8.2 to 16.7)  | 12.2 (4.6 to 24.8)  | 12.0 (8.6 to 16.2)  |
| Headache: Moderate                    | 0 (0.0 to 33.6)    | 18.0 (13.4 to 23.3) | 4.1 (0.5 to 14.0)   | 15.3 (11.4 to 19.8) |
| Headache: Severe                      | 0 (0.0 to 33.6)    | 0.8 (0.1 to 2.9)    | 0 (0.0 to 7.3)      | 0.6 (0.1 to 2.3)    |
| Headache: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Chills: Any                           | 11.1 (0.3 to 48.2) | 12.0 (8.2 to 16.7)  | 10.2 (3.4 to 22.2)  | 11.7 (8.3 to 15.8)  |
| Chills: Mild                          | 11.1 (0.3 to 48.2) | 7.2 (4.3 to 11.1)   | 4.1 (0.5 to 14.0)   | 6.8 (4.3 to 10.2)   |
| Chills: Moderate                      | 0 (0.0 to 33.6)    | 4.8 (2.5 to 8.2)    | 6.1 (1.3 to 16.9)   | 4.9 (2.8 to 7.9)    |
| Chills: Severe                        | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Chills: Grade 4                       | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Vomiting: Any                         | 0 (0.0 to 33.6)    | 4.8 (2.5 to 8.2)    | 2.0 (0.1 to 10.9)   | 4.2 (2.3 to 7.1)    |
| Vomiting: Mild                        | 0 (0.0 to 33.6)    | 2.4 (0.9 to 5.2)    | 2.0 (0.1 to 10.9)   | 2.3 (0.9 to 4.6)    |
| Vomiting: Moderate                    | 0 (0.0 to 33.6)    | 2.4 (0.9 to 5.2)    | 0 (0.0 to 7.3)      | 1.9 (0.7 to 4.2)    |
| Vomiting: Severe                      | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Vomiting: Grade 4                     | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| Diarrhoea: Any                        | 11.1 (0.3 to 48.2) | 16.8 (12.4 to 22.0) | 8.2 (2.3 to 19.6)   | 15.3 (11.4 to 19.8) |
| Diarrhoea: Mild                       | 11.1 (0.3 to 48.2) | 10.0 (6.6 to 14.4)  | 6.1 (1.3 to 16.9)   | 9.4 (6.4 to 13.2)   |
| Diarrhoea: Moderate                   | 0 (0.0 to 33.6)    | 6.4 (3.7 to 10.2)   | 2.0 (0.1 to 10.9)   | 5.5 (3.2 to 8.7)    |
| Diarrhoea: Severe                     | 0 (0.0 to 33.6)    | 0.4 (0.0 to 2.2)    | 0 (0.0 to 7.3)      | 0.3 (0.0 to 1.8)    |
| Diarrhoea: Grade 4                    | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| New or worsened muscle pain: Any      | 11.1 (0.3 to 48.2) | 18.0 (13.4 to 23.3) | 18.4 (8.8 to 32.0)  | 17.9 (13.7 to 22.6) |
| New or worsened muscle pain: Mild     | 11.1 (0.3 to 48.2) | 8.0 (5.0 to 12.1)   | 10.2 (3.4 to 22.2)  | 8.4 (5.6 to 12.1)   |
| New or worsened muscle pain: Moderate | 0 (0.0 to 33.6)    | 10.0 (6.6 to 14.4)  | 8.2 (2.3 to 19.6)   | 9.4 (6.4 to 13.2)   |
| New or worsened muscle pain: Severe   | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| New or worsened muscle pain: Grade 4  | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| New or worsened joint pain: Any       | 11.1 (0.3 to 48.2) | 12.8 (8.9 to 17.6)  | 12.2 (4.6 to 24.8)  | 12.7 (9.2 to 16.9)  |
| New or worsened joint pain: Mild      | 11.1 (0.3 to 48.2) | 6.4 (3.7 to 10.2)   | 6.1 (1.3 to 16.9)   | 6.5 (4.0 to 9.9)    |
| New or worsened joint pain: Moderate  | 0 (0.0 to 33.6)    | 6.4 (3.7 to 10.2)   | 6.1 (1.3 to 16.9)   | 6.2 (3.8 to 9.5)    |
| New or worsened joint pain: Severe    | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |
| New or worsened joint pain: Grade 4   | 0 (0.0 to 33.6)    | 0 (0.0 to 1.5)      | 0 (0.0 to 7.3)      | 0 (0.0 to 1.2)      |



Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSB

|                 |                                                                                                                             |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With AEs From Vaccination Through 1 Month After Vaccination: SSB <sup>[25]</sup> <sup>[26]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs from study vaccination on Day 1 up to 1 month after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received the study intervention.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From vaccination on Day 1 up to 1 month after vaccination

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSB: Group 1: 12-17 years | SSB: Group 2: 18-55 years | SSB: Group 3: >55 years | SSB Total Study Participants |
|-----------------------------------|---------------------------|---------------------------|-------------------------|------------------------------|
| Subject group type                | Reporting group           | Reporting group           | Reporting group         | Subject analysis set         |
| Number of subjects analysed       | 9                         | 253                       | 49                      | 311                          |
| Units: Percentage of Participants |                           |                           |                         |                              |
| number (confidence interval 95%)  | 0 (0.0 to 33.6)           | 2.4 (0.9 to 5.1)          | 2.0 (0.1 to 10.9)       | 2.3 (0.9 to 4.6)             |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSB

|                 |                                                                                                                                         |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Participants With SAEs From Vaccination Through 6 Months After the Study Vaccination: SSB <sup>[27]</sup> <sup>[28]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------|

End point description:

An SAE was defined as any untoward medical occurrence at any dose that resulted in any of the following outcomes: death; life-threatening; required inpatient hospitalization or prolongation of existing

hospitalization; persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic; or considered as an important medical event. Percentage of participants reporting SAEs from study vaccination on Day 1 up to 6 months after the study vaccination were reported in this endpoint. Exact 2-sided CI was based on Clopper and Pearson method. Safety population included all participants who received the study intervention.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From vaccination on Day 1 up to 6 months after vaccination

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned for this endpoint.

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values                  | SSB: Group 1:<br>12-17 years | SSB: Group 2:<br>18-55 years | SSB: Group 3:<br>>55 years | SSB Total<br>Study<br>Participants |
|-----------------------------------|------------------------------|------------------------------|----------------------------|------------------------------------|
| Subject group type                | Reporting group              | Reporting group              | Reporting group            | Subject analysis set               |
| Number of subjects analysed       | 9                            | 253                          | 49                         | 311                                |
| Units: Percentage of participants |                              |                              |                            |                                    |
| number (confidence interval 95%)  | 0 (0.0 to 33.6)              | 0.8 (0.1 to 2.8)             | 2.0 (0.1 to 10.9)          | 1.0 (0.2 to 2.8)                   |

## Statistical analyses

No statistical analyses for this end point

### Primary: Geometric Mean Ratio (GMR) of the SARS-CoV-2 XBB.1.5-Neutralizing Titers 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

|                 |                                                                                                                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Ratio (GMR) of the SARS-CoV-2 XBB.1.5-Neutralizing Titers 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

GMTs and 2-sided 95% CIs were calculated by exponentiating the least square (LS) means and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline assay results (log scale), age and vaccine group as covariates. Assay results below the LLOQ were set to 0.5\*LLOQ. GMT is reported in descriptive section and GMR in statistical analysis section. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint.

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 1 month after vaccination

|                                          |                               |                                             |  |  |
|------------------------------------------|-------------------------------|---------------------------------------------|--|--|
| <b>End point values</b>                  | SSB: Vaccine-Naïve Substudy B | SSB Control: Vaccine-Experienced Substudy A |  |  |
| Subject group type                       | Subject analysis set          | Subject analysis set                        |  |  |
| Number of subjects analysed              | 298                           | 295                                         |  |  |
| Units: Titer                             |                               |                                             |  |  |
| geometric mean (confidence interval 95%) | 4951.6 (4222.8 to 5806.2)     | 2566.5 (2186.8 to 3012.1)                   |  |  |

## Statistical analyses

|                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                                                                                                                                                                  | Vaccine-Naïve SSB vs Vaccine-Experienced SSA                                |
| Statistical analysis description:                                                                                                                                                                                                                                                                                                                                                                                  |                                                                             |
| GMRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the difference in LS means (Substudy B - Substudy A) and the corresponding CIs based on analysis of log-transformed assay results using a linear regression model with baseline assay results (log scale), age and vaccine group as covariates. Noninferiority of GMR was met if the lower limit of the 95% CI was greater than 0.67. |                                                                             |
| Comparison groups                                                                                                                                                                                                                                                                                                                                                                                                  | SSB: Vaccine-Naïve Substudy B v SSB Control: Vaccine-Experienced Substudy A |
| Number of subjects included in analysis                                                                                                                                                                                                                                                                                                                                                                            | 593                                                                         |
| Analysis specification                                                                                                                                                                                                                                                                                                                                                                                             | Pre-specified                                                               |
| Analysis type                                                                                                                                                                                                                                                                                                                                                                                                      | non-inferiority                                                             |
| Parameter estimate                                                                                                                                                                                                                                                                                                                                                                                                 | Geometric mean ratio                                                        |
| Point estimate                                                                                                                                                                                                                                                                                                                                                                                                     | 1.93                                                                        |
| Confidence interval                                                                                                                                                                                                                                                                                                                                                                                                |                                                                             |
| level                                                                                                                                                                                                                                                                                                                                                                                                              | 95 %                                                                        |
| sides                                                                                                                                                                                                                                                                                                                                                                                                              | 2-sided                                                                     |
| lower limit                                                                                                                                                                                                                                                                                                                                                                                                        | 1.52                                                                        |
| upper limit                                                                                                                                                                                                                                                                                                                                                                                                        | 2.44                                                                        |

## Primary: Difference in Percentages of Participants With Seroresponse to the XBB.1.5 Strain 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Difference in Percentages of Participants With Seroresponse to the XBB.1.5 Strain 1 Month After BNT162b2 (Omi XBB.1.5): COVID-19 Vaccine-Naïve Participants in SSB Versus Vaccine-Experienced Participants in SSA |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                   |
| Seroresponse was defined as achieving $\geq 4$ -fold rise from baseline. If the baseline measurement was below the LLOQ, the postvaccination assay result of $\geq 4 \times$ LLOQ was considered a seroresponse. Percentage of participants with seroresponse is reported in descriptive section and percentage difference in statistical analysis section. Evaluable immunogenicity population included all eligible assigned participants who received the study intervention to which they were assigned, had at least 1 valid and determinate immunogenicity result from the blood sample collected within 28 to 42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. Here, Number of Participants Analysed signifies number of participants evaluable for this endpoint. |                                                                                                                                                                                                                   |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Primary                                                                                                                                                                                                           |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                   |
| At 1 month after vaccination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                   |

| End point values                  | SSB: Vaccine-Naïve Substudy B | SSB Control: Vaccine-Experienced Substudy A |  |  |
|-----------------------------------|-------------------------------|---------------------------------------------|--|--|
| Subject group type                | Subject analysis set          | Subject analysis set                        |  |  |
| Number of subjects analysed       | 298                           | 295                                         |  |  |
| Units: Percentage of participants |                               |                                             |  |  |
| number (confidence interval 95%)  | 84.9 (80.3 to 88.8)           | 73.9 (68.5 to 78.8)                         |  |  |

## Statistical analyses

| Statistical analysis title                                                                                                                                                                                                                                                                                               | Vaccine-Naïve SSB vs Vaccine-Experienced SSA                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Statistical analysis description:                                                                                                                                                                                                                                                                                        |                                                                             |
| 2-Sided CI, based on the Miettinen and Nurminen method stratified by baseline neutralizing titer category (< median, >= median) and age group (< median, >= median). Noninferiority based on seroresponse was declared if the lower limit of the 2-sided 95% CI for the difference in percentages was greater than -10%. |                                                                             |
| Comparison groups                                                                                                                                                                                                                                                                                                        | SSB: Vaccine-Naïve Substudy B v SSB Control: Vaccine-Experienced Substudy A |
| Number of subjects included in analysis                                                                                                                                                                                                                                                                                  | 593                                                                         |
| Analysis specification                                                                                                                                                                                                                                                                                                   | Pre-specified                                                               |
| Analysis type                                                                                                                                                                                                                                                                                                            | non-inferiority                                                             |
| Parameter estimate                                                                                                                                                                                                                                                                                                       | Percentage Difference                                                       |
| Point estimate                                                                                                                                                                                                                                                                                                           | 7.31                                                                        |
| Confidence interval                                                                                                                                                                                                                                                                                                      |                                                                             |
| level                                                                                                                                                                                                                                                                                                                    | 95 %                                                                        |
| sides                                                                                                                                                                                                                                                                                                                    | 2-sided                                                                     |
| lower limit                                                                                                                                                                                                                                                                                                              | 1.34                                                                        |
| upper limit                                                                                                                                                                                                                                                                                                              | 13.28                                                                       |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

SSA & SSB: Systematic assessment: Local reactions, systemic events: Day 1 to Day 7 after vaccination (vacc.); Non-systematic assessment: SAEs: Day 1 of vacc. up to 6 months after study vacc. & Non-SAEs: Day 1 of vaccination up to 1 month after study vacc.

Adverse event reporting additional description:

Same event may appear as both AE and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |    |
|--------------------|----|
| Dictionary version | 26 |
|--------------------|----|

### Reporting groups

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | SSA: Group 1: 12-17 years |
|-----------------------|---------------------------|

Reporting group description:

Participants aged 12 to 17 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | SSA: Group 2: 18-55 years |
|-----------------------|---------------------------|

Reporting group description:

Participants aged 18 to 55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | SSA: Group 3: >55 years |
|-----------------------|-------------------------|

Reporting group description:

Participants aged >55 years who received at least three prior doses of US-authorized mRNA COVID-19 vaccine with the most recent dose being the Omicron BA.4/BA.5 received at least 150 days prior to the study vaccination were included. Participants received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | SSB: Group 1: 12-17 years |
|-----------------------|---------------------------|

Reporting group description:

Participants aged 12-17 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                       |                           |
|-----------------------|---------------------------|
| Reporting group title | SSB: Group 2: 18-55 years |
|-----------------------|---------------------------|

Reporting group description:

Participants aged 18-55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | SSB: Group 3: >55 years |
|-----------------------|-------------------------|

Reporting group description:

Participants aged >55 years who were previously exposed to SARS-CoV-2 and were COVID-19 vaccine-naïve received a single dose of BNT162b2 (Omi XBB.1.5) 30 mcg via IM route on Day 1 of this study.

| <b>Serious adverse events</b>                                       | SSA: Group 1: 12-17 years | SSA: Group 2: 18-55 years | SSA: Group 3: >55 years |
|---------------------------------------------------------------------|---------------------------|---------------------------|-------------------------|
| Total subjects affected by serious adverse events                   |                           |                           |                         |
| subjects affected / exposed                                         | 1 / 30 (3.33%)            | 0 / 174 (0.00%)           | 4 / 208 (1.92%)         |
| number of deaths (all causes)                                       | 0                         | 0                         | 1                       |
| number of deaths resulting from adverse events                      | 0                         | 0                         | 1                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                           |                           |                         |
| Invasive lobular breast carcinoma                                   |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 1 / 208 (0.48%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 1                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Cardiac disorders                                                   |                           |                           |                         |
| Cardiac arrest                                                      |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 1 / 208 (0.48%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 1                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 1                   |
| Gastrointestinal disorders                                          |                           |                           |                         |
| Small intestinal obstruction                                        |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 0 / 208 (0.00%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Respiratory, thoracic and mediastinal disorders                     |                           |                           |                         |
| Pulmonary embolism                                                  |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 1 / 208 (0.48%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 1                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Dyspnoea                                                            |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 0 / 208 (0.00%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Renal and urinary disorders                                         |                           |                           |                         |
| Acute kidney injury                                                 |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 30 (0.00%)            | 0 / 174 (0.00%)           | 1 / 208 (0.48%)         |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 1                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Paroxysmal nocturnal                                                |                           |                           |                         |

|                                                 |                |                 |                 |
|-------------------------------------------------|----------------|-----------------|-----------------|
| haemoglobinuria                                 |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 174 (0.00%) | 1 / 208 (0.48%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Infections and infestations                     |                |                 |                 |
| Cellulitis                                      |                |                 |                 |
| subjects affected / exposed                     | 1 / 30 (3.33%) | 0 / 174 (0.00%) | 0 / 208 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Appendicitis                                    |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 174 (0.00%) | 0 / 208 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                |                 |                 |
| Hyponatraemia                                   |                |                 |                 |
| subjects affected / exposed                     | 0 / 30 (0.00%) | 0 / 174 (0.00%) | 1 / 208 (0.48%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0           |

| <b>Serious adverse events</b>                                       | SSB: Group 1: 12-17 years | SSB: Group 2: 18-55 years | SSB: Group 3: >55 years |
|---------------------------------------------------------------------|---------------------------|---------------------------|-------------------------|
| Total subjects affected by serious adverse events                   |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 9 (0.00%)             | 2 / 253 (0.79%)           | 1 / 49 (2.04%)          |
| number of deaths (all causes)                                       | 0                         | 0                         | 0                       |
| number of deaths resulting from adverse events                      | 0                         | 0                         | 0                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                           |                           |                         |
| Invasive lobular breast carcinoma                                   |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 9 (0.00%)             | 0 / 253 (0.00%)           | 0 / 49 (0.00%)          |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Cardiac disorders                                                   |                           |                           |                         |
| Cardiac arrest                                                      |                           |                           |                         |
| subjects affected / exposed                                         | 0 / 9 (0.00%)             | 0 / 253 (0.00%)           | 0 / 49 (0.00%)          |
| occurrences causally related to treatment / all                     | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| deaths causally related to treatment / all                          | 0 / 0                     | 0 / 0                     | 0 / 0                   |
| Gastrointestinal disorders                                          |                           |                           |                         |

|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| Small intestinal obstruction                    |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 1 / 49 (2.04%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |               |                 |                |
| Pulmonary embolism                              |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Dyspnoea                                        |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 253 (0.40%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Renal and urinary disorders                     |               |                 |                |
| Acute kidney injury                             |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Paroxysmal nocturnal haemoglobinuria            |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Infections and infestations                     |               |                 |                |
| Cellulitis                                      |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Appendicitis                                    |               |                 |                |
| subjects affected / exposed                     | 0 / 9 (0.00%) | 1 / 253 (0.40%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |
| Metabolism and nutrition disorders              |               |                 |                |
| Hyponatraemia                                   |               |                 |                |



|                                                 |               |                 |                |
|-------------------------------------------------|---------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 9 (0.00%) | 0 / 253 (0.00%) | 0 / 49 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0           | 0 / 0          |

Frequency threshold for reporting non-serious adverse events: 1 %

| <b>Non-serious adverse events</b>                     | SSA: Group 1: 12-17 years | SSA: Group 2: 18-55 years | SSA: Group 3: >55 years |
|-------------------------------------------------------|---------------------------|---------------------------|-------------------------|
| Total subjects affected by non-serious adverse events |                           |                           |                         |
| subjects affected / exposed                           | 27 / 30 (90.00%)          | 154 / 174 (88.51%)        | 134 / 208 (64.42%)      |
| Nervous system disorders                              |                           |                           |                         |
| Restless arm syndrome                                 |                           |                           |                         |
| subjects affected / exposed                           | 1 / 30 (3.33%)            | 0 / 174 (0.00%)           | 0 / 208 (0.00%)         |
| occurrences (all)                                     | 1                         | 0                         | 0                       |
| Headache (HEADACHE)                                   |                           |                           |                         |
| alternative assessment type: Systematic               |                           |                           |                         |
| subjects affected / exposed                           | 11 / 30 (36.67%)          | 76 / 174 (43.68%)         | 54 / 208 (25.96%)       |
| occurrences (all)                                     | 11                        | 76                        | 54                      |
| Blood and lymphatic system disorders                  |                           |                           |                         |
| Lymphadenopathy                                       |                           |                           |                         |
| subjects affected / exposed                           | 0 / 30 (0.00%)            | 2 / 174 (1.15%)           | 0 / 208 (0.00%)         |
| occurrences (all)                                     | 0                         | 2                         | 0                       |
| General disorders and administration site conditions  |                           |                           |                         |
| Fatigue (FATIGUE)                                     |                           |                           |                         |
| alternative assessment type: Systematic               |                           |                           |                         |
| subjects affected / exposed                           | 17 / 30 (56.67%)          | 99 / 174 (56.90%)         | 73 / 208 (35.10%)       |
| occurrences (all)                                     | 17                        | 99                        | 73                      |
| Injection site erythema (REDNESS)                     |                           |                           |                         |
| alternative assessment type: Systematic               |                           |                           |                         |
| subjects affected / exposed                           | 3 / 30 (10.00%)           | 7 / 174 (4.02%)           | 12 / 208 (5.77%)        |
| occurrences (all)                                     | 3                         | 7                         | 12                      |
| Chills (CHILLS)                                       |                           |                           |                         |
| alternative assessment type: Systematic               |                           |                           |                         |
| subjects affected / exposed                           | 6 / 30 (20.00%)           | 16 / 174 (9.20%)          | 19 / 208 (9.13%)        |
| occurrences (all)                                     | 6                         | 16                        | 19                      |
| Fatigue                                               |                           |                           |                         |

|                                            |                  |                    |                    |
|--------------------------------------------|------------------|--------------------|--------------------|
| subjects affected / exposed                | 0 / 30 (0.00%)   | 2 / 174 (1.15%)    | 2 / 208 (0.96%)    |
| occurrences (all)                          | 0                | 2                  | 2                  |
| Injection site pruritus                    |                  |                    |                    |
| subjects affected / exposed                | 1 / 30 (3.33%)   | 0 / 174 (0.00%)    | 0 / 208 (0.00%)    |
| occurrences (all)                          | 1                | 0                  | 0                  |
| Injection site swelling (SWELLING)         |                  |                    |                    |
| alternative assessment type:<br>Systematic |                  |                    |                    |
| subjects affected / exposed                | 5 / 30 (16.67%)  | 13 / 174 (7.47%)   | 12 / 208 (5.77%)   |
| occurrences (all)                          | 5                | 13                 | 12                 |
| Injection site pain (PAIN)                 |                  |                    |                    |
| alternative assessment type:<br>Systematic |                  |                    |                    |
| subjects affected / exposed                | 24 / 30 (80.00%) | 132 / 174 (75.86%) | 107 / 208 (51.44%) |
| occurrences (all)                          | 24               | 132                | 107                |
| Injection site pain                        |                  |                    |                    |
| subjects affected / exposed                | 0 / 30 (0.00%)   | 0 / 174 (0.00%)    | 4 / 208 (1.92%)    |
| occurrences (all)                          | 0                | 0                  | 4                  |
| Pyrexia (FEVER)                            |                  |                    |                    |
| alternative assessment type:<br>Systematic |                  |                    |                    |
| subjects affected / exposed                | 5 / 30 (16.67%)  | 7 / 174 (4.02%)    | 8 / 208 (3.85%)    |
| occurrences (all)                          | 5                | 7                  | 8                  |
| Non-cardiac chest pain                     |                  |                    |                    |
| subjects affected / exposed                | 0 / 30 (0.00%)   | 2 / 174 (1.15%)    | 1 / 208 (0.48%)    |
| occurrences (all)                          | 0                | 2                  | 1                  |
| Gastrointestinal disorders                 |                  |                    |                    |
| Diarrhoea                                  |                  |                    |                    |
| subjects affected / exposed                | 0 / 30 (0.00%)   | 3 / 174 (1.72%)    | 0 / 208 (0.00%)    |
| occurrences (all)                          | 0                | 3                  | 0                  |
| Vomiting (VOMITING)                        |                  |                    |                    |
| alternative assessment type:<br>Systematic |                  |                    |                    |
| subjects affected / exposed                | 0 / 30 (0.00%)   | 4 / 174 (2.30%)    | 0 / 208 (0.00%)    |
| occurrences (all)                          | 0                | 4                  | 0                  |
| Diarrhoea (DIARRHEA)                       |                  |                    |                    |
| alternative assessment type:<br>Systematic |                  |                    |                    |
| subjects affected / exposed                | 0 / 30 (0.00%)   | 21 / 174 (12.07%)  | 18 / 208 (8.65%)   |
| occurrences (all)                          | 0                | 21                 | 18                 |

|                                                                                                                                                                            |                      |                         |                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-------------------------|-------------------------|
| Gastroesophageal reflux disease<br>subjects affected / exposed<br>occurrences (all)                                                                                        | 0 / 30 (0.00%)<br>0  | 2 / 174 (1.15%)<br>2    | 0 / 208 (0.00%)<br>0    |
| Reproductive system and breast disorders<br>Dysmenorrhoea<br>subjects affected / exposed<br>occurrences (all)                                                              | 1 / 30 (3.33%)<br>1  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |
| Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all)                                                                                               | 1 / 30 (3.33%)<br>1  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |
| Psychiatric disorders<br>Depression<br>subjects affected / exposed<br>occurrences (all)                                                                                    | 1 / 30 (3.33%)<br>1  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |
| Musculoskeletal and connective tissue disorders<br>Myalgia (MUSCLE PAIN)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 7 / 30 (23.33%)<br>7 | 38 / 174 (21.84%)<br>38 | 25 / 208 (12.02%)<br>25 |
| Arthralgia (JOINT PAIN)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                  | 5 / 30 (16.67%)<br>5 | 25 / 174 (14.37%)<br>25 | 16 / 208 (7.69%)<br>16  |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)                                                                                                      | 0 / 30 (0.00%)<br>0  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |
| Infections and infestations<br>Sialoadenitis<br>subjects affected / exposed<br>occurrences (all)                                                                           | 1 / 30 (3.33%)<br>1  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all)                                                               | 1 / 30 (3.33%)<br>1  | 0 / 174 (0.00%)<br>0    | 0 / 208 (0.00%)<br>0    |

|                                   |                           |                           |                         |
|-----------------------------------|---------------------------|---------------------------|-------------------------|
| <b>Non-serious adverse events</b> | SSB: Group 1: 12-17 years | SSB: Group 2: 18-55 years | SSB: Group 3: >55 years |
|-----------------------------------|---------------------------|---------------------------|-------------------------|

|                                                                                                                                                                          |                     |                         |                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------------|------------------------|
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed                                                                                     | 4 / 9 (44.44%)      | 167 / 253 (66.01%)      | 25 / 49 (51.02%)       |
| Nervous system disorders<br>Restless arm syndrome<br>subjects affected / exposed<br>occurrences (all)                                                                    | 0 / 9 (0.00%)<br>0  | 0 / 253 (0.00%)<br>0    | 0 / 49 (0.00%)<br>0    |
| Headache (HEADACHE)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)                                                       | 1 / 9 (11.11%)<br>1 | 76 / 253 (30.04%)<br>76 | 8 / 49 (16.33%)<br>8   |
| Blood and lymphatic system disorders<br>Lymphadenopathy<br>subjects affected / exposed<br>occurrences (all)                                                              | 0 / 9 (0.00%)<br>0  | 1 / 253 (0.40%)<br>1    | 0 / 49 (0.00%)<br>0    |
| General disorders and administration site conditions<br>Fatigue (FATIGUE)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | 87 / 253 (34.39%)<br>87 | 12 / 49 (24.49%)<br>12 |
| Injection site erythema (REDNESS)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)                                         | 0 / 9 (0.00%)<br>0  | 22 / 253 (8.70%)<br>22  | 1 / 49 (2.04%)<br>1    |
| Chills (CHILLS)<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all)                                                           | 1 / 9 (11.11%)<br>1 | 30 / 253 (11.86%)<br>30 | 5 / 49 (10.20%)<br>5   |
| Fatigue<br>subjects affected / exposed<br>occurrences (all)                                                                                                              | 0 / 9 (0.00%)<br>0  | 0 / 253 (0.00%)<br>0    | 0 / 49 (0.00%)<br>0    |
| Injection site pruritus<br>subjects affected / exposed<br>occurrences (all)                                                                                              | 0 / 9 (0.00%)<br>0  | 0 / 253 (0.00%)<br>0    | 0 / 49 (0.00%)<br>0    |
| Injection site swelling (SWELLING)<br>alternative assessment type: Systematic                                                                                            |                     |                         |                        |

|                                            |                |                    |                  |
|--------------------------------------------|----------------|--------------------|------------------|
| subjects affected / exposed                | 1 / 9 (11.11%) | 30 / 253 (11.86%)  | 5 / 49 (10.20%)  |
| occurrences (all)                          | 1              | 30                 | 5                |
| Injection site pain (PAIN)                 |                |                    |                  |
| alternative assessment type:<br>Systematic |                |                    |                  |
| subjects affected / exposed                | 4 / 9 (44.44%) | 142 / 253 (56.13%) | 18 / 49 (36.73%) |
| occurrences (all)                          | 4              | 142                | 18               |
| Injection site pain                        |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 5 / 253 (1.98%)    | 0 / 49 (0.00%)   |
| occurrences (all)                          | 0              | 5                  | 0                |
| Pyrexia (FEVER)                            |                |                    |                  |
| alternative assessment type:<br>Systematic |                |                    |                  |
| subjects affected / exposed                | 1 / 9 (11.11%) | 6 / 253 (2.37%)    | 3 / 49 (6.12%)   |
| occurrences (all)                          | 1              | 6                  | 3                |
| Non-cardiac chest pain                     |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 0 / 253 (0.00%)    | 0 / 49 (0.00%)   |
| occurrences (all)                          | 0              | 0                  | 0                |
| Gastrointestinal disorders                 |                |                    |                  |
| Diarrhoea                                  |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 0 / 253 (0.00%)    | 0 / 49 (0.00%)   |
| occurrences (all)                          | 0              | 0                  | 0                |
| Vomiting (VOMITING)                        |                |                    |                  |
| alternative assessment type:<br>Systematic |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 12 / 253 (4.74%)   | 1 / 49 (2.04%)   |
| occurrences (all)                          | 0              | 12                 | 1                |
| Diarrhoea (DIARRHEA)                       |                |                    |                  |
| alternative assessment type:<br>Systematic |                |                    |                  |
| subjects affected / exposed                | 1 / 9 (11.11%) | 42 / 253 (16.60%)  | 4 / 49 (8.16%)   |
| occurrences (all)                          | 1              | 42                 | 4                |
| Gastrooesophageal reflux disease           |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 0 / 253 (0.00%)    | 0 / 49 (0.00%)   |
| occurrences (all)                          | 0              | 0                  | 0                |
| Reproductive system and breast disorders   |                |                    |                  |
| Dysmenorrhoea                              |                |                    |                  |
| subjects affected / exposed                | 0 / 9 (0.00%)  | 0 / 253 (0.00%)    | 0 / 49 (0.00%)   |
| occurrences (all)                          | 0              | 0                  | 0                |

|                                                                                                                                                                                                                                                                                                                                                                                          |                                                                          |                                                                                    |                                                                             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| Heavy menstrual bleeding<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                             | 0 / 9 (0.00%)<br>0                                                       | 0 / 253 (0.00%)<br>0                                                               | 0 / 49 (0.00%)<br>0                                                         |
| Psychiatric disorders<br>Depression<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                                  | 0 / 9 (0.00%)<br>0                                                       | 0 / 253 (0.00%)<br>0                                                               | 0 / 49 (0.00%)<br>0                                                         |
| Musculoskeletal and connective tissue disorders<br>Myalgia (MUSCLE PAIN)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Arthralgia (JOINT PAIN)<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pain in extremity<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1<br><br>1 / 9 (11.11%)<br>1<br><br>0 / 9 (0.00%)<br>0 | 45 / 253 (17.79%)<br>45<br><br>32 / 253 (12.65%)<br>32<br><br>0 / 253 (0.00%)<br>0 | 9 / 49 (18.37%)<br>9<br><br>6 / 49 (12.24%)<br>6<br><br>1 / 49 (2.04%)<br>1 |
| Infections and infestations<br>Sialoadenitis<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                                         | 0 / 9 (0.00%)<br>0                                                       | 0 / 253 (0.00%)<br>0                                                               | 0 / 49 (0.00%)<br>0                                                         |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                             | 0 / 9 (0.00%)<br>0                                                       | 0 / 253 (0.00%)<br>0                                                               | 0 / 49 (0.00%)<br>0                                                         |

**More information**

**Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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**Interruptions (globally)**

Were there any global interruptions to the trial? No

**Limitations and caveats**

None reported