# Clinical trial results:
# A Phase 4, Open-Label, Single-Arm Trial to Describe the Safety, Tolerability, And Immunogenicity of Trumenba® When Administered to Immunocompromised Participants 10 Years of Age

## Summary

| | |
|---|---|
| EudraCT number | 2018-002588-24 |
| Trial protocol | CZ PL |
| Global end of trial date | 06 September 2023 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 17 March 2024 |
| First version publication date | 17 March 2024 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | B1971060 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04893811 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235E 42nd Street, New York, United States, NY 10017 |
| Public contact | PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

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 | Final |
| Date of interim/final analysis | 01 November 2023 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 06 September 2023 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main immunogenicity objective of the study was to describe the immune response induced by 2 doses of Trumenba in immunocompromised subjects and historical age-matched healthy subjects as measured by serum bactericidal assay using human complement (hSBA) performed with 4 primary Neisseria meningitidis serogroup B (MnB) test strains, 2 expressing an LP2086 subfamily A protein and 2 expressing an LP2086 subfamily B protein. The main safety objective of the study was to evaluate the safety profile of Trumenba in immunocompromised subjects and historical age-matched healthy subjects.

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 subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 18 August 2021 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 6 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Czechia: 16 |
| Country: Number of subjects enrolled | Finland: 5 |
| Country: Number of subjects enrolled | Poland: 17 |
| Country: Number of subjects enrolled | Türkiye: 24 |
| Country: Number of subjects enrolled | United States: 42 |
| Worldwide total number of subjects | 104 |
| EEA total number of subjects | 38 |

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) | 4 |
| Adolescents (12-17 years) | 14 |
| Adults (18-64 years) | 83 |
| From 65 to 84 years | 3 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

A total of 53 subjects were enrolled at multiple sites. Study started from 18 August 2021 and completed on 06 September 2023.

### Pre-assignment

Screening details:

Age- and sex-matched healthy subjects from groups 2 or 4 (Trumenba) of previously completed Phase 3 study B1971057 Stage 1 were used as control arm in this study; their historical data was used as reference for safety and immunogenicity analysis.

### Period 1

| | |
|---|---|
| Period 1 title | Vaccination phase |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Trumenba |

Arm description:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 millilitre (mL), intramuscularly (IM) on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Trumenba |
| Investigational medicinal product code | PF-05212366 |
| Other name | Bivalent rLP2086 and meningococcal serogroup B vaccine |
| Pharmaceutical forms | Powder and solvent for suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 mL, IM on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| | |
|---|---|
| **Arm title** | Trumenba: From B1971057, Control Arm |

Arm description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1(NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Trumenba |
| Investigational medicinal product code | PF-05212366 |
| Other name | Bivalent rLP2086 and meningococcal serogroup B vaccine |
| Pharmaceutical forms | Powder and solvent for suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL IM injection at Month 0 (first dose along with Menveo) and at Month 6 (second dose, single) during Stage 1 of the study B1971057.

| | |
|---|---|
| Investigational medicinal product name | Meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) |
| Investigational medicinal product code | |
| Other name | Menveo |

| | |
|---|---|
| Pharmaceutical forms | Concentrate and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL IM injection at Month 0 (first dose along with Trumenba) during Stage 1 of the study B1971057.

| **Number of subjects in period 1** | Trumenba | Trumenba: From B1971057, Control Arm |
|---|---|---|
| Started | 53 | 51 |
| Vaccination 1 | 53 | 51 |
| Vaccination 2 | 47 | 47 |
| Completed | 47 | 47 |
| Not completed | 6 | 4 |
| Consent withdrawn by subject | 2 | 1 |
| No longer meets eligibility criteria | - | 1 |
| Death | 1 | - |
| Unspecified | - | 1 |
| Lost to follow-up | 1 | 1 |
| Protocol deviation | 2 | - |

## Period 2

| | |
|---|---|
| Period 2 title | Follow-up phase |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Trumenba |

Arm description:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 mL, IM on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| | |
|---|---|
| Arm type | No intervention |

No investigational medicinal product assigned in this arm

| | |
|---|---|
| **Arm title** | Trumenba: From B1971057, Control Arm |

Arm description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1 (NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

| | |
|---|---|
| Arm type | No intervention |

No investigational medicinal product assigned in this arm

| **Number of subjects in period 2** | Trumenba | Trumenba: From B1971057, Control Arm |
|---|---|---|
| Started | 47 | 47 |
| Completed | 47 | 46 |
| Not completed | 0 | 1 |
| Lost to follow-up | - | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Trumenba |
| Reporting group description: | |
| Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 millilitre (mL), intramuscularly (IM) on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6). | |
| Reporting group title | Trumenba: From B1971057, Control Arm |
| Reporting group description: | |
| Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1(NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study. | |

| Reporting group values | Trumenba | Trumenba: From B1971057, Control Arm | Total |
|---|---|---|---|
| Number of subjects | 53 | 51 | 104 |
| Age Categorical<br>Units: Subjects | | | |
| Children (2-11 years) | 2 | 2 | 4 |
| Adolescents (12-17 years) | 8 | 6 | 14 |
| Adults (18-64 years) | 40 | 43 | 83 |
| From 65-84 years | 3 | 0 | 3 |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 32.5 | 22.2 | |
| standard deviation | ± 16.55 | ± 4.26 | - |
| Gender Categorical<br>Units: Subjects | | | |
| Female | 23 | 21 | 44 |
| Male | 30 | 30 | 60 |
| Race<br>Units: Subjects | | | |
| White | 53 | 46 | 99 |
| Black or African American | 0 | 3 | 3 |
| Asian | 0 | 2 | 2 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 0 | 7 | 7 |
| Not Hispanic/Latino | 53 | 44 | 97 |

## End points

### End points reporting groups

| Reporting group title | Trumenba |
|---|---|

Reporting group description:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 millilitre (mL), intramuscularly (IM) on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| Reporting group title | Trumenba: From B1971057, Control Arm |
|---|---|

Reporting group description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1(NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

| Reporting group title | Trumenba |
|---|---|

Reporting group description:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 mL, IM on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| Reporting group title | Trumenba: From B1971057, Control Arm |
|---|---|

Reporting group description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1 (NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

| Subject analysis set title | Trumenba: From B1971057, Control Arm |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1(NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

### Primary: Percentage of Subjects With hSBA Titer => LLOQ for Each of the 4 Primary MnB Test Strains at 1 Month After Vaccination 2

| End point title | Percentage of Subjects With hSBA Titer => LLOQ for Each of the 4 Primary MnB Test Strains at 1 Month After Vaccination 2[1][2] |
|---|---|

End point description:

The percentage of subjects who achieved an hSBA titer (A22) =>1:16, and hSBA titer (A56, B24, and B44) =>1:8 are reported. Evaluable immunogenicity set included all subjects who were eligible through 1 month after Vaccination 2, received the study vaccination at Visit 1 and Visit 3 as planned, had blood drawn for assay testing within the required time frames at Visit 1 (before Vaccination 1) and 1 month after Vaccination 2 (28-42 days after Visit 3), had at least 1 valid and determinate assay result 1 month after Vaccination 2, received no prohibited vaccines or medications through Visit 4, and had no major protocol deviations through Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given immunogenicity set. Here, "n" signifies number of subjects evaluable for specified rows.

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

End point timeframe:

1 Month after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 44 | 44 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| PMB80 (A22) (n =44, 43) | 75.0 (59.7 to 86.8) | 95.3 (84.2 to 99.4) | | |
| PMB2001 (A56) (n =44, 44) | 90.9 (78.3 to 97.5) | 100.0 (92.0 to 100.0) | | |
| PMB2948 (B24) (n =44, 44) | 70.5 (54.8 to 83.2) | 81.8 (67.3 to 91.8) | | |
| PMB2707 (B44) (n =43, 42) | 79.1 (64.0 to 90.0) | 92.9 (80.5 to 98.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titer => Lower Limit of Quantitation (LLOQ) for Each of the 4 Primary Neisseria Meningitidis Serogroup B (MnB) Test Strains at Baseline

| End point title | Percentage of Subjects With Serum Bactericidal Assay Using Human Complement (hSBA) Titer => Lower Limit of Quantitation (LLOQ) for Each of the 4 Primary Neisseria Meningitidis Serogroup B (MnB) Test Strains at Baseline[3][4] |
|---|---|

End point description:

The percentage of subjects who achieved an hSBA titer (A22) =>1:16, and hSBA titer (A56, B24, and B44) =>1:8 are reported. Evaluable immunogenicity set included all subjects who were eligible through 1 month after Vaccination 2, received the study vaccination at Visit 1 and Visit 3 as planned, had blood drawn for assay testing within the required time frames at Visit 1 (before vaccination 1) and 1 month after Vaccination 2 (28-42 Days after Visit 3), had at least 1 valid and determinate assay result 1 Month after Vaccination 2, received no prohibited vaccines or medications through visit 4, and had no major protocol deviations through visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given immunogenicity set. Here, "n" signifies number of subjects evaluable for specified rows.

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

End point timeframe:

Baseline (Before Vaccination 1)

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 43 | 44 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| PMB80 (A22) (n =43, 42) | 32.6 (19.1 to 48.5) | 31.0 (17.6 to 47.1) | | |
| PMB2001 (A56) (n =43, 43) | 25.6 (13.5 to 41.2) | 23.3 (11.8 to 38.6) | | |
| PMB2948 (B24) (n =42, 43) | 2.4 (0.1 to 12.6) | 23.3 (11.8 to 38.6) | | |
| PMB2707 (B44) (n =43, 44) | 9.3 (2.6 to 22.1) | 11.4 (3.8 to 24.6) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions Within 7 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Local Reactions Within 7 Days After Vaccination 1[5][6] |
|---|---|

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration were recorded in electronic diary (e-diary. Redness and swelling measured and recorded in caliper units. Each caliper unit = 0.5 cm. Redness and swelling were graded as mild (>2.0 to 5.0cm), moderate (>5.0 to 10.0cm) and severe (>10.0cm). Pain at injection site graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). Vaccination 1 safety set = all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" = number of subjects present in the given safety set.

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

End point timeframe:

Within 7 Days after Vaccination 1

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 18.9 (9.4 to 32.0) | 11.8 (4.4 to 23.9) | | |

| | | | | |
|---|---|---|---|---|
| Redness: Mild | 5.7 (1.2 to 15.7) | 5.9 (1.2 to 16.2) | | |
| Redness: Moderate | 9.4 (3.1 to 20.7) | 3.9 (0.5 to 13.5) | | |
| Redness: Severe | 3.8 (0.5 to 13.0) | 2.0 (0.0 to 10.4) | | |
| Swelling: Any | 22.6 (12.3 to 36.2) | 11.8 (4.4 to 23.9) | | |
| Swelling: Mild | 7.5 (2.1 to 18.2) | 7.8 (2.2 to 18.9) | | |
| Swelling: Moderate | 15.1 (6.7 to 27.6) | 3.9 (0.5 to 13.5) | | |
| Swelling: Severe | 0 (0.0 to 6.7) | 0 (0.0 to 7.0) | | |
| Pain at injection site: Any | 86.8 (74.7 to 94.5) | 80.4 (66.9 to 90.2) | | |
| Pain at injection site: Mild | 41.5 (28.1 to 55.9) | 47.1 (32.9 to 61.5) | | |
| Pain at injection site: Moderate | 32.1 (19.9 to 46.3) | 33.3 (20.8 to 47.9) | | |
| Pain at injection site: Severe | 13.2 (5.5 to 25.3) | 0 (0.0 to 7.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Local Reactions Within 7 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting Local Reactions Within 7 Days After Vaccination 2[7][8] |
|---|---|

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration recorded in e-diary. Redness and swelling measured and recorded in caliper units. Each caliper unit = 0.5 cm. Redness and swelling graded as mild (>2.0-5.0cm), moderate (>5.0-10.0cm) and severe (>10.0cm). Pain at injection site graded as mild (didn't interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). Vaccination 2 safety set = all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. "Number of Subjects Analyzed": subjects present in the given safety set. All subjects in given safety set are not contributing to data for each specified rows but were evaluable for this endpoint. "n": subjects analysed for specified rows.

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

End point timeframe:

Within 7 Days after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (n =45, 43) | 20.0 (9.6 to 34.6) | 7.0 (1.5 to 19.1) | | |
| Redness: Mild (n =45, 43) | 6.7 (1.4 to 18.3) | 2.3 (0.1 to 12.3) | | |
| Redness: Moderate (n =45, 43) | 11.1 (3.7 to 24.1) | 4.7 (0.6 to 15.8) | | |
| Redness: Severe (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Swelling: Any (n =45, 43) | 26.7 (14.6 to 41.9) | 4.7 (0.6 to 15.8) | | |
| Swelling: Mild (n =45, 43) | 13.3 (5.1 to 26.8) | 0 (0.0 to 8.2) | | |
| Swelling: Moderate (n =45, 43) | 13.3 (5.1 to 26.8) | 4.7 (0.6 to 15.8) | | |
| Swelling: Severe (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |
| Pain at injection site: Any (n =45, 43) | 93.3 (81.7 to 98.6) | 60.5 (44.4 to 75.0) | | |
| Pain at injection site: Mild (n =45, 43) | 44.4 (29.6 to 60.0) | 30.2 (17.2 to 46.1) | | |
| Pain at injection site: Moderate (n =45, 43) | 35.6 (21.9 to 51.2) | 27.9 (15.3 to 43.7) | | |
| Pain at injection site: Severe (n =45, 43) | 13.3 (5.1 to 26.8) | 2.3 (0.1 to 12.3) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Systemic Events Within 7 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Systemic Events Within 7 Days After Vaccination 1[9][10] |
|---|---|

End point description:

Systemic events included: fever, fatigue, headache, chills, muscle pain, joint pain, vomitting, and diarrhea. Fever (>=38.0 degree [deg] Celsius [C]) and classified as 38.0-38.4, 38.5-38.9, 39.0 40.0 and >40.0 deg C. Headache, fatigue, chills, muscle pain and joint pain graded as mild (didn't interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting graded as mild (1-2 times in 24 hrs), moderate (>2 times in 24 hrs) and severe (required intravenous [IV] hydration). Diarrhea graded as mild (2-3 loose stools in 24 hrs), moderate (4-5 loose stools in 24 hrs) and severe (>=6 in 24 hrs). Vaccination 1 safety set was used. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. "Number of Subjects Analyzed"= number of subjects in the given safety set.

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

End point timeframe:

Within 7 Days after Vaccination 1

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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Fever: More than or equal (=>)38.0 deg C | 3.8 (0.5 to 13.0) | 2.0 (0.0 to 10.4) | | |
| Fever: 38.0 to 38.4 deg C | 1.9 (0.0 to 10.1) | 0 (0.0 to 7.0) | | |
| Fever: More than (>)38.4 to 38.9 deg C | 0 (0.0 to 6.7) | 2.0 (0.0 to 10.4) | | |
| Fever: >38.9 to 40.0 deg C | 1.9 (0.0 to 10.1) | 0 (0.0 to 7.0) | | |
| Fever: >40.0 deg C | 0 (0.0 to 6.7) | 0 (0.0 to 7.0) | | |
| Fatigue: Any | 54.7 (40.4 to 68.4) | 51.0 (36.6 to 65.2) | | |
| Fatigue: Mild | 26.4 (15.3 to 40.3) | 39.2 (25.8 to 53.9) | | |
| Fatigue: Moderate | 22.6 (12.3 to 36.2) | 11.8 (4.4 to 23.9) | | |
| Fatigue: Severe | 5.7 (1.2 to 15.7) | 0 (0.0 to 7.0) | | |
| Headache: Any | 41.5 (28.1 to 55.9) | 29.4 (17.5 to 43.8) | | |
| Headache: Mild | 18.9 (9.4 to 32.0) | 25.5 (14.3 to 39.6) | | |
| Headache: Moderate | 18.9 (9.4 to 32.0) | 2.0 (0.0 to 10.4) | | |
| Headache: Severe | 3.8 (0.5 to 13.0) | 2.0 (0.0 to 10.4) | | |
| Chills: Any | 15.1 (6.7 to 27.6) | 19.6 (9.8 to 33.1) | | |
| Chills: Mild | 11.3 (4.3 to 23.0) | 17.6 (8.4 to 30.9) | | |
| Chills: Moderate | 1.9 (0.0 to 10.1) | 2.0 (0.0 to 10.4) | | |
| Chills: Severe | 1.9 (0.0 to 10.1) | 0 (0.0 to 7.0) | | |
| Muscle Pain: Any | 26.4 (15.3 to 40.3) | 23.5 (12.8 to 37.5) | | |
| Muscle Pain: Mild | 15.1 (6.7 to 27.6) | 11.8 (4.4 to 23.9) | | |
| Muscle Pain: Moderate | 9.4 (3.1 to 20.7) | 9.8 (3.3 to 21.4) | | |
| Muscle Pain: Severe | 1.9 (0.0 to 10.1) | 2.0 (0.0 to 10.4) | | |
| Joint Pain: Any | 22.6 (12.3 to 36.2) | 19.6 (9.8 to 33.1) | | |
| Joint Pain: Mild | 9.4 (3.1 to 20.7) | 11.8 (4.4 to 23.9) | | |
| Joint Pain: Moderate | 9.4 (3.1 to 20.7) | 5.9 (1.2 to 16.2) | | |

| | | | | |
|---|---|---|---|---|
| Joint Pain: Severe | 3.8 (0.5 to 13.0) | 2.0 (0.0 to 10.4) | | |
| Vomiting: Any | 1.9 (0.0 to 10.1) | 2.0 (0.0 to 10.4) | | |
| Vomiting: Mild | 1.9 (0.0 to 10.1) | 2.0 (0.0 to 10.4) | | |
| Vomiting: Moderate | 0 (0.0 to 6.7) | 0 (0.0 to 7.0) | | |
| Vomiting: Severe | 0 (0.0 to 6.7) | 0 (0.0 to 7.0) | | |
| Diarrhea: Any | 9.4 (3.1 to 20.7) | 11.8 (4.4 to 23.9) | | |
| Diarrhea: Mild | 9.4 (3.1 to 20.7) | 5.9 (1.2 to 16.2) | | |
| Diarrhea: Moderate | 0 (0.0 to 6.7) | 5.9 (1.2 to 16.2) | | |
| Diarrhea: Severe | 0 (0.0 to 6.7) | 0 (0.0 to 7.0) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Systemic Events Within 7 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting Systemic Events Within 7 Days After Vaccination 2[11][12] |
|---|---|

End point description:

Systemic events included: fever, fatigue, headache, chills, muscle pain, joint pain, vomiting, diarrhea. Fever (>=38.0 deg C) and classified as 38.0-38.4, 38.5-38.9, 39.0 40.0 and >40.0 deg C. Headache, fatigue, chills, muscle pain and joint pain graded as mild (didn't interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting graded as mild (1-2 times in 24 hrs), moderate (>2 times in 24 hrs) and severe (required IV hydration). Diarrhea graded as mild (2-3 loose stools in 24 hrs), moderate (4-5 loose stools in 24 hrs) and severe (>=6 in 24 hrs). Vaccination 2 safety set was used. Historical data of the age- and sex-matched healthy subjects relevant for endpoint used for control arm. "Number of Subjects Analyzed"= subjects in the given safety set. All subjects in given safety set are not contributing to data for each specified rows but were evaluable for endpoint. "n" = subjects analysed for specified rows.

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

End point timeframe:

Within 7 Days after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |

| | | | | |
|---|---|---|---|---|
| Fever: =>38.0 deg C (n =45, 43) | 2.2 (0.1 to 11.8) | 2.3 (0.1 to 12.3) | | |
| Fever: 38.0 to 38.4 deg C (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Fever: >38.4 to 38.9 deg C (n =45, 43) | 0 (0.0 to 7.9) | 2.3 (0.1 to 12.3) | | |
| Fever: >38.9 to 40.0 deg C (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |
| Fever: >40.0 deg C (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |
| Fatigue: Any (n =45, 43) | 53.3 (37.9 to 68.3) | 41.9 (27.0 to 57.9) | | |
| Fatigue: Mild (n =45, 43) | 24.4 (12.9 to 39.5) | 23.3 (11.8 to 38.6) | | |
| Fatigue: Moderate (n =45, 43) | 24.4 (12.9 to 39.5) | 14.0 (5.3 to 27.9) | | |
| Fatigue: Severe (n =45, 43) | 4.4 (0.5 to 15.1) | 4.7 (0.6 to 15.8) | | |
| Headache: Any (n =45, 43) | 35.6 (21.9 to 51.2) | 30.2 (17.2 to 46.1) | | |
| Headache: Mild (n =45, 43) | 6.7 (1.4 to 18.3) | 23.3 (11.8 to 38.6) | | |
| Headache: Moderate (n =45, 43) | 22.2 (11.2 to 37.1) | 7.0 (1.5 to 19.1) | | |
| Headache: Severe (n =45, 43) | 6.7 (1.4 to 18.3) | 0 (0.0 to 8.2) | | |
| Chills: Any (n =45, 43) | 8.9 (2.5 to 21.2) | 14.0 (5.3 to 27.9) | | |
| Chills: Mild (n =45, 43) | 4.4 (0.5 to 15.1) | 11.6 (3.9 to 25.1) | | |
| Chills: Moderate (n =45, 43) | 2.2 (0.1 to 11.8) | 2.3 (0.1 to 12.3) | | |
| Chills: Severe (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Muscle Pain: Any (n =45, 43) | 13.3 (5.1 to 26.8) | 11.6 (3.9 to 25.1) | | |
| Muscle Pain: Mild (n =45, 43) | 4.4 (0.5 to 15.1) | 7.0 (1.5 to 19.1) | | |
| Muscle Pain: Moderate (n =45, 43) | 8.9 (2.5 to 21.2) | 2.3 (0.1 to 12.3) | | |
| Muscle Pain: Severe (n =45, 43) | 0 (0.0 to 7.9) | 2.3 (0.1 to 12.3) | | |
| Joint Pain: Any (n =45, 43) | 20.0 (9.6 to 34.6) | 16.3 (6.8 to 30.7) | | |
| Joint Pain: Mild (n =45, 43) | 6.7 (1.4 to 18.3) | 14.0 (5.3 to 27.9) | | |
| Joint Pain: Moderate (n =45, 43) | 11.1 (3.7 to 24.1) | 0 (0.0 to 8.2) | | |
| Joint Pain: Severe (n =45, 43) | 2.2 (0.1 to 11.8) | 2.3 (0.1 to 12.3) | | |
| Vomiting: Any (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Vomiting: Mild (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Vomiting: Moderate (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |
| Vomiting: Severe (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |
| Diarrhea: Any (n =45, 43) | 8.9 (2.5 to 21.2) | 4.7 (0.6 to 15.8) | | |
| Diarrhea: Mild (n =45, 43) | 6.7 (1.4 to 18.3) | 4.7 (0.6 to 15.8) | | |
| Diarrhea: Moderate (n =45, 43) | 2.2 (0.1 to 11.8) | 0 (0.0 to 8.2) | | |
| Diarrhea: Severe (n =45, 43) | 0 (0.0 to 7.9) | 0 (0.0 to 8.2) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Use of Antipyretic Medication Within 7 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Use of Antipyretic Medication Within 7 Days After Vaccination 1[13][14] |
|---|---|

End point description:

Vaccination 1 safety set included all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

Within 7 Days after Vaccination 1

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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 34.0 (21.5 to 48.3) | 9.8 (3.3 to 21.4) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Use of Antipyretic Medication Within 7 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting Use of Antipyretic Medication Within 7 Days After Vaccination 2[15][16] |
|---|---|

End point description:

Vaccination 2 safety set included all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects who were analysed for this endpoint and

contributed to the data.

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

End point timeframe:

Within 7 Days after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 45 | 43 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 28.9 (16.4 to 44.3) | 7.0 (1.5 to 19.1) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Adverse Events (AEs) During 30 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Adverse Events (AEs) During 30 Days After Vaccination 1[17][18] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs excluded local reactions and systematic events. Vaccination 1 safety set included all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, “Number of Subjects Analyzed” signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 1

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 26.4 (15.3 to 40.3) | 9.8 (3.3 to 21.4) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting AEs During 30 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting AEs During 30 Days After Vaccination 2[19][20] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs excluded local reactions and systematic events. Vaccination 2 safety set included all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 12.8 (4.8 to 25.7) | 12.8 (4.8 to 25.7) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting AEs During the Vaccination Phase

| End point title | Percentage of Subjects Reporting AEs During the Vaccination Phase[21][22] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs excluded local reactions and systematic events. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Vaccination Phase: From Vaccination 1 through one Month after Vaccination 2 (approximately 7 Months)

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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 60.4 (46.0 to 73.5) | 41.2 (27.6 to 55.8) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting AEs During 30 Days After any Vaccination

| End point title | Percentage of Subjects Reporting AEs During 30 Days After any Vaccination[23][24] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. AEs excluded local reactions and systematic events. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

30 Days after any 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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 34.0 (21.5 to 48.3) | 17.6 (8.4 to 30.9) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs During 30 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting SAEs During 30 Days After Vaccination 2[25][26] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect or that was considered to be an important medical event. Vaccination 2 safety set included all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 2

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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0 (0.0 to 7.5) | 0 (0.0 to 7.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs During 30 Days After any Vaccination

| End point title | Percentage of Subjects Reporting SAEs During 30 Days After any Vaccination[27][28] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect or that was considered to be an important medical event. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

30 Days after any 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 9.4 (3.1 to 20.7) | 0 (0.0 to 7.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs During the Vaccination Phase

| End point title | Percentage of Subjects Reporting SAEs During the Vaccination Phase[29][30] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect or that was considered to be an important medical event. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Vaccination Phase: From Vaccination 1 through 1 Month after Vaccination 2 (approximately 7 Months)

Notes:

[29] - 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.

[30] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 17.0 (8.1 to 29.8) | 0 (0.0 to 7.0) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Serious Adverse Events (SAEs) During 30 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Serious Adverse Events (SAEs) During 30 Days After Vaccination 1[31][32] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect or that was considered to be an important medical event. Vaccination 1 safety set included all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 1

Notes:

[31] - 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.

[32] - 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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 9.4 (3.1 to 20.7) | 0 (0.0 to 7.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs During the Entire Study

| End point title | Percentage of Subjects Reporting SAEs During the Entire |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Entire Study: From Vaccination 1 through 6 Months after Vaccination 2 (approximately 12 Months)

Notes:

[33] - 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.

[34] - 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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 18.9 (9.4 to 32.0) | 2.0 (0.0 to 10.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Medically Attended Adverse Event (MAEs) During 30 Days After Vaccination 1

| End point title | Percentage of Subjects Reporting Medically Attended Adverse Event (MAEs) During 30 Days After Vaccination 1[35][36] |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Vaccination 1 safety set included all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 1

Notes:

[35] - 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.

[36] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 20.8 (10.8 to 34.1) | 5.9 (1.2 to 16.2) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting MAEs During 30 Days After Vaccination 2

| End point title | Percentage of Subjects Reporting MAEs During 30 Days After Vaccination 2[37][38] |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Vaccination 2 safety set included all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Days after Vaccination 2

Notes:

[37] - 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.

[38] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 12.8 (4.8 to 25.7) | 4.3 (0.5 to 14.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting SAEs During the Follow-up Phase

| End point title | Percentage of Subjects Reporting SAEs During the Follow-up Phase[39][40] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect or that was considered to be an important medical event. Follow-up safety set included all subjects who received at least 1 dose of study intervention and for whom safety information was available from after Visit 4 up to and including Visit 5 Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

Follow-up Phase: From 1 Month after Vaccination 2 through 6 Months after Vaccination 2 (approximately 5 Months)

Notes:

[39] - 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.

[40] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 44 | 48 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 4.5 (0.6 to 15.5) | 2.1 (0.1 to 11.1) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting MAEs During the Follow-up Phase

| End point title | Percentage of Subjects Reporting MAEs During the Follow-up Phase[41][42] |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Follow-up safety set included all subjects who received at least 1 dose of study intervention and for whom safety information was available from after Visit 4 up to and including Visit 5. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

Follow-up Phase: From 1 Month after Vaccination 2 through 6 Months after Vaccination 2 (approximately 5 Months)

Notes:

[41] - 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.

[42] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 44 | 48 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 15.9 (6.6 to 30.1) | 10.4 (3.5 to 22.7) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting MAEs During 30 days After any Vaccination

| End point title | Percentage of Subjects Reporting MAEs During 30 days After any Vaccination[43][44] |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy

subjects relevant for this endpoint used for control arm.

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

End point timeframe:

30 Days after any Vaccination

Notes:

[43] - 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.

[44] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 30.2 (18.3 to 44.3) | 9.8 (3.3 to 21.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting MAEs During the Vaccination Phase

| End point title | Percentage of Subjects Reporting MAEs During the Vaccination Phase[45][46] |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Vaccination Phase: From Vaccination 1 through 1 Month after Vaccination 2 (approximately 7 Months)

Notes:

[45] - 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.

[46] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 54.7 (40.4 to | 29.4 (17.5 to | | |

| | |
|---|---|
| 68.4) | 43.8) |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting MAEs During the Entire Study

| End point title | Percentage of Subjects Reporting MAEs During the Entire |
|---|---|

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Entire Study: From Vaccination 1 through 6 Months after Vaccination 2 (approximately 12 Months)

Notes:

[47] - 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.

[48] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 60.4 (46.0 to 73.5) | 31.4 (19.1 to 45.9) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Subjects Reporting Immediate AEs After Vaccination 1

| End point title | Percentage of Subjects Reporting Immediate AEs After Vaccination 1[49][50] |
|---|---|

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after study intervention administration. Vaccination 1 safety set included all subjects who received the first dose of study intervention at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Minutes post Vaccination 1

Notes:

[49] - 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.

[50] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0 (0.0 to 6.7) | 2.0 (0.0 to 10.4) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects Reporting Immediate AEs After Vaccination 2

| End point title | Percentage of Subjects Reporting Immediate AEs After Vaccination 2[51][52] |
|---|---|

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after study intervention administration. Vaccination 2 safety set included all subjects who received the second dose of study intervention at Visit 3 and for whom safety information was available from Visit 3 up to and including Visit 4. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

30 Minutes post Vaccination 2

Notes:

[51] - 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.

[52] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 47 | 47 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0 (0.0 to 7.5) | 0 (0.0 to 7.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects With NDCMC During the Entire Study

| End point title | Percentage of Subjects With NDCMC During the Entire |
|---|---|

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Entire Study: From Vaccination 1 through 6 Months after Vaccination 2 (approximately 12 Months)

Notes:

[53] - 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.

[54] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 1.9 (0.0 to 10.1) | 0 (0.0 to 7.0) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Days Subjects Missed School or Work Because of AEs During the Vaccination Phase

| End point title | Number of Days Subjects Missed School or Work Because of AEs During the Vaccination Phase[55][56] |
|---|---|

End point description:

An AE is any untoward medical occurrence in a subject or clinical study subject, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant

for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects evaluable for this endpoint.

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

End point timeframe:

Vaccination Phase: From Vaccination 1 through 1 Month after Vaccination 2 (approximately 7 Months)

Notes:

[55] - 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.

[56] - 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: Subject analysis set has been created to report data for control arm.

| **End point values** | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 32 | 21 | | |
| Units: Days | | | | |
| arithmetic mean (standard deviation) | 12.7 (± 7.6) | 2.5 (± 2.3) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects With NDCMC During the Follow-up Phase

| End point title | Percentage of Subjects With NDCMC During the Follow-up Phase[57][58] |
|---|---|

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Follow-up safety set included all subjects who received at least 1 dose of study intervention and for whom safety information was available from after Visit 4 up to and including Visit 5. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm. Here, "Number of Subjects Analyzed" signifies number of subjects present in the given safety set.

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

End point timeframe:

Follow-up Phase: From 1 Month after Vaccination 2 through 6 Months after Vaccination 2 (approximately 5 Months)

Notes:

[57] - 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.

[58] - 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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 44 | 48 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0 (0.0 to 8.0) | 0 (0.0 to 7.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Subjects With Newly Diagnosed Chronic Medical Condition (NDCMC) During the Vaccination Phase

| End point title | Percentage of Subjects With Newly Diagnosed Chronic Medical Condition (NDCMC) During the Vaccination Phase[59][60] |
|---|---|

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Safety set included all enrolled subjects who received at least 1 dose of the study intervention and have safety data reported after vaccination. Historical data of the age- and sex-matched healthy subjects relevant for this endpoint used for control arm.

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

End point timeframe:

Vaccination Phase: From Vaccination 1 through 1 Month after Vaccination 2 (approximately 7 Months)

Notes:

[59] - 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.

[60] - 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: Subject analysis set has been created to report data for control arm.

| End point values | Trumenba | Trumenba: From B1971057, Control Arm | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 53 | 51 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 1.9 (0.0 to 10.1) | 0 (0.0 to 7.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Local reactions, systemic events within 7 days of each vaccination; SAEs and Non-SAEs: From Day 1 of vaccination up to 6 months after last study vaccination (approximately 12 months)

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 subject and non-serious in another, or a subject may have experienced both SAE and non-SAE. For study B1971057 MedDRA version 25.1 was used and for study B1971060 MedDRA version 26.0 was used.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 26.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Trumenba: From B1971057, Control Arm |

Reporting group description:

Age- and sex-matched healthy subjects from group 2 or 4 (Trumenba groups) from Phase 3 study B1971057 Stage 1(NCT ID: NCT04893811/EudraCT Number: 2016-004421-17) were randomly selected and included in this group. This arm served as a control arm for the study.

| | |
|---|---|
| Reporting group title | Trumenba |

Reporting group description:

Immunocompromised subjects >=10 years of age with asplenia (anatomic or functional) or complement deficiency, received Trumenba 0.5 mL, IM on Day 1 of Visit 1 (Month 0) and Visit 3 (Month 6).

| Serious adverse events | Trumenba: From B1971057, Control Arm | Trumenba | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 10 / 53 (18.87%) | |
| number of deaths (all causes) | 0 | 1 | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral neck fracture | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |

| | | | |
|---|---|---|---|
| Acute myocardial infarction | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 4 / 53 (7.55%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Gastrointestinal disorders | | | |
| Pancreatitis chronic | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchiectasis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 2 / 53 (3.77%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 0 %

| **Non-serious adverse events** | Trumenba: From B1971057, Control Arm | Trumenba | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 49 / 51 (96.08%) | 51 / 53 (96.23%) | |
| Vascular disorders | | | |
| Secondary hypertension | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 7 / 51 (13.73%) | 17 / 53 (32.08%) | |
| occurrences (all) | 8 | 24 | |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 2 / 53 (3.77%) | |
| occurrences (all) | 2 | 3 | |
| Injection site pain (PAIN AT INJECTION SITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 45 / 51 (88.24%) | 48 / 53 (90.57%) | |
| occurrences (all) | 67 | 88 | |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 11 / 51 (21.57%) | 11 / 53 (20.75%) | |
| occurrences (all) | 16 | 12 | |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 27 / 51 (52.94%) | 31 / 53 (58.49%) | |
| occurrences (all) | 44 | 53 | |
| Fatigue | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 1 / 53 (1.89%) | |
| occurrences (all) | 2 | 1 | |
| Injection site pain | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 0 / 53 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Vocal cord polyp | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Cough | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |
| SARS-CoV-2 test positive | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 2 / 53 (3.77%) | |
| occurrences (all) | 0 | 2 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 2 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |

| | | | |
|---|---|---|---|
| Injury, poisoning and procedural complications | | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fall | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Incisional hernia | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Limb injury | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Skin laceration | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Soft tissue injury | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Nervous system disorders | | | |
| Syncope | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 0 / 53 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache (HEADACHE) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 21 / 51 (41.18%) | 25 / 53 (47.17%) | |
| occurrences (all) | 28 | 38 | |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 2 | |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eye disorders | | | |
| Periorbital swelling | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Eye haemorrhage | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Gastrointestinal disorders | | | |
| Constipation | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 0 / 53 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Nausea | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Diarrhoea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 7 / 51 (13.73%) | 8 / 53 (15.09%) | |
| occurrences (all) | 8 | 9 | |
| Vomiting (VOMITING) | | | |
| alternative assessment type: | | | |

| | | | |
|---|---|---|---|
| Systematic | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 2 / 53 (3.77%) | |
| occurrences (all) | 1 | 2 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 6 / 51 (11.76%) | 14 / 53 (26.42%) | |
| occurrences (all) | 9 | 19 | |
| Acne | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 53 (1.89%) | |
| occurrences (all) | 1 | 1 | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Night sweats | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 13 / 51 (25.49%) | 14 / 53 (26.42%) | |
| occurrences (all) | 17 | 21 | |
| Myalgia (MUSCLE PAIN) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 14 / 51 (27.45%) | 16 / 53 (30.19%) | |
| occurrences (all) | 17 | 20 | |
| Back pain | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 3 / 53 (5.66%) | |
| occurrences (all) | 0 | 3 | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 53 (1.89%) | |
| occurrences (all) | 1 | 1 | |
| Soft tissue swelling | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 51 (3.92%) | 0 / 53 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 5 / 53 (9.43%) | |
| occurrences (all) | 0 | 5 | |
| Urethritis mycoplasmal | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Tonsillitis streptococcal | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 4 / 51 (7.84%) | 2 / 53 (3.77%) | |
| occurrences (all) | 5 | 2 | |
| Tracheitis | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Urinary tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 53 (1.89%) | |
| occurrences (all) | 1 | 1 | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Furuncle | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Influenza | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 5 / 53 (9.43%) | |
| occurrences (all) | 0 | 5 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 1 / 53 (1.89%) | |
| occurrences (all) | 1 | 1 | |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Otitis media | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Otitis media bacterial | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 4 / 51 (7.84%) | 0 / 53 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 4 / 53 (7.55%) | |
| occurrences (all) | 0 | 4 | |
| Urethritis | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Viral pharyngitis | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 2 / 53 (3.77%) | |
| occurrences (all) | 0 | 2 | |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 1 / 51 (1.96%) | 0 / 53 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Metabolism and nutrition disorders | | | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 51 (0.00%) | 1 / 53 (1.89%) | |
| occurrences (all) | 0 | 1 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported