ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Trumenba suspension for injection in pre-filled syringe

Meningococcal group B vaccine (recombinant, adsorbed)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

Neisseria meningitidis serogroup B fHbp subfamily A[1,2,3] 60 micrograms

Neisseria meningitidis serogroup B fHbp subfamily B[1,2,3] 60 micrograms

[1] Recombinant lipidated fHbp (factor H binding protein)
[2] Produced in *Escherichia coli* cells by recombinant DNA technology
[3] Adsorbed on aluminium phosphate (0.25 milligram aluminium per dose)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White liquid suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Trumenba is indicated for active immunisation of individuals 10 years and older to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B.

See section 5.1 for information on the immune response against specific serogroup B strains.

The use of this vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

Posology

Primary series
2 doses: (0.5 ml each) administered at a 6 month interval (see section 5.1).

3 doses: 2 doses (0.5 ml each) administered at least 1 month apart, followed by a third dose at least 4 months after the second dose (see section 5.1).

Booster dose
A booster dose should be considered following either dosing regimen for individuals at continued risk of invasive meningococcal disease (see section 5.1).

Other paediatric populations
Safety and efficacy of Trumenba in children younger than 10 years of age have not been established. Currently available data for children 1 to 9 years of age are described in sections 4.8 and 5.1; however, no recommendation on a posology can be made as data are limited.

Method of administration

For intramuscular injection only. The preferred site for injection is the deltoid muscle of the upper arm.

For instructions on the handling of the vaccine before administration, see section 6.6.

There are no data available on the interchangeability of Trumenba with other meningococcal group B vaccines to complete the vaccination series.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In order to improve the traceability of biological medicinal products, the tradename and batch number of the administered product should be clearly recorded.

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

As with other injectable vaccines, syncope (fainting) can occur in association with administration of Trumenba. Procedures should be in place to avoid injury from fainting.

Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, should not result in the deferral of vaccination.

Do not inject intravenously, intradermally, or subcutaneously.

Trumenba should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration.

Persons with familial complement deficiencies (for example, C5 or C3 deficiencies) and persons receiving treatments that inhibit terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *Neisseria meningitidis* serogroup B, even if they develop antibodies following vaccination with Trumenba.

As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients.

Limitations of clinical trials
There are no data on the use of Trumenba in immunocompromised individuals. Immunocompromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Trumenba.

There are limited data on the use of Trumenba in individuals 40 to 65 years of age and there are no data on the use of Trumenba in individuals older than 65 years of age.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose. Individuals on low sodium diets can be informed that this medicinal product is essentially sodium-free.

4.5 Interaction with other medicinal products and other forms of interaction

Trumenba can be given concomitantly with any of the following vaccines: Tetanus Toxoid, Reduced Diphtheria Toxoid, Acellular Pertussis, and Inactivated Poliovirus Vaccine (TdaP-IPV), Quadrivalent Human Papillomavirus vaccine (HPV4), Meningococcal Serogroups A, C, W, Y conjugate vaccine (MenACWY) and Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap).

When given concomitantly with other vaccines Trumenba must be administered at a separate injection site.

Trumenba should not be mixed with other vaccines in the same syringe.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of Trumenba in pregnant women. The potential risk for pregnant women is unknown. Nevertheless, vaccination should not be withheld when there is a clear risk of exposure to meningococcal infection.

Reproduction studies performed in female rabbits have revealed no evidence of impaired female fertility or harm to the foetus due to Trumenba.

Breast-feeding

It is unknown whether Trumenba is excreted in human milk. Trumenba should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to fertility in females (see section 5.3).

Trumenba has not been evaluated for impairment of fertility in males.

4.7 Effects on ability to drive and use machines

Trumenba has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4.8 may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The safety profile presented is based on analysis of approximately 17,000 subjects (1 year of age and older) who have been vaccinated with at least 1 dose of Trumenba in completed clinical studies.

In over 16,000 subjects ≥ 10 years of age studied, the most common adverse reactions were headache, diarrhoea, nausea, muscle pain, joint pain, fatigue, chills, and injection site pain, swelling and redness.

Adverse reactions following booster vaccination in 301 subjects 15 to 23 years of age were similar to adverse reactions during the primary Trumenba vaccination series approximately 4 years earlier.

List of adverse reactions

Adverse reactions reported in clinical studies of subjects 10 years of age and older are listed in decreasing order of frequency and seriousness.

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from available data)

Immune system disorder
Not known: Allergic reactions*

Nervous system disorders
Very Common: Headache

Gastrointestinal disorders
Very Common: Diarrhoea; nausea
Common: Vomiting

Musculoskeletal and connective tissue disorders
Very Common: Muscle pain (myalgia); joint pain (arthralgia)

General disorders and administration site conditions
Very Common: Chills; fatigue; redness (erythema), swelling (induration) and pain at injection site
Common: Fever ≥ 38 °C (pyrexia)

* Reported in the postmarketing experience. Because this reaction was derived from spontaneous reports, the frequency could not be determined and is thus considered as not known.

In a study of 220 toddlers 1 to < 2 years of age, the following adverse reactions occurred at a frequency of very common (≥ 1/10): drowsiness, irritability (fussiness), loss of or decreased appetite, fever, and injection site pain, swelling and redness.

In a study of 294 children 2 to 9 years of age, the following adverse reactions occurred at a frequency of very common (≥ 1/10): headache, diarrhoea, vomiting, muscle pain, joint pain, fever, fatigue, and injection site pain, swelling and redness.

In clinical studies, fever (≥ 38°C) occurred more frequently as subject age decreased. Of subjects 1 to < 2 years of age, 37.3% reported fever; of subjects 2 to 9 years of age, 24.5% reported fever; of subjects 10 to 18 years of age, 9.8% reported fever; and of subjects 18 to 25 years of age, 4.4% reported fever. Fever followed a predictable pattern after vaccination: onset occurred within 2 to 4 days, lasted 1 day, and was mild to moderate in severity. Fever rate and severity tended to decrease with subsequent Trumenba vaccinations.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Experience of overdose is limited. In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines; ATC code: J07AH09

Mechanism of action

Trumenba is a vaccine composed of 2 recombinant lipidated factor H binding protein (fHbp) variants. fHbp is found on the surface of meningococcal bacteria and helps bacteria to avoid host immune defenses. fHbp variants segregate into 2 immunologically distinct subfamilies, A and B, and over 96% of meningococcal serogroup B isolates in Europe express fHbp variants from either subfamily on the bacterial surface.

Immunisation with Trumenba, which contains one fHbp variant each from subfamily A and B, is intended to stimulate the production of bactericidal antibodies that recognise fHbp expressed by meningococci. The Meningococcal Antigen Surface Expression (MEASURE) assay was developed to relate the level of fHbp surface expression to killing of meningococcal serogroup B strains in serum bactericidal assays with human complement (hSBAs). A survey of over 2,150 different invasive meningococcal serogroup B isolates collected from 2000-2014 in 7 European countries, the US and Canada demonstrated that over 91% of all meningococcal serogroup B isolates expressed sufficient levels of fHbp to be susceptible to bactericidal killing by vaccine-induced antibodies.

Clinical efficacy

The efficacy of Trumenba has not been evaluated through clinical trials. Vaccine efficacy has been inferred by demonstrating the induction of serum bactericidal antibody responses to 4 meningococcal serogroup B test strains (see the Immunogenicity section). The 4 test strains express fHbp variants representing the 2 subfamilies (A and B) and, when taken together, are representative of meningococcal serogroup B strains causing invasive disease.

Immunogenicity

Protection against invasive meningococcal disease is mediated by serum bactericidal antibodies to bacterial surface antigens. Bactericidal antibodies act in concert with human complement to kill meningococci. This process is measured *in vitro* with hSBA for meningococcal serogroup B. An hSBA titre of ≥ 1:4 is assumed to be protective against meningococcal disease. In the immunogenicity analysis for Trumenba, a more conservative hSBA titre threshold of ≥ 1:8 or 1:16 was applied, depending on the hSBA strain.

Vaccine coverage was investigated using four primary representative meningococcal serogroup B test strains: two expressing subfamily A fHbp (variants A22 and A56) and two expressing subfamily B fHbp (variants B24 and B44). To support and further extend the breadth of vaccine coverage, an additional 10 meningococcal serogroup B test strains were used; these included six expressing subfamily A fHbp (variants A06, A07, A12, A15, A19 and A29) and four expressing subfamily B fHbp (variants B03, B09, B15 and B16).

Immunogenicity in subjects 10 years of age and older

The immunogenicity of Trumenba described in this section includes results from Phase 2 and Phase 3 clinical studies:

- Following the 2-dose schedule (0 and 6 months) in subjects 10 to 25 years of age in the US and Europe (Study B1971057);
- Following the 3-dose schedule (0, 2, and 6 months) in subjects 10 to 25 years of age globally (Studies B1971009 and B1971016); and
- Following the 2-dose (0 and 6 months) and 3-dose schedules (0, 1-2, and 6 months) in subjects 11 to 18 years of age in Europe (Study B1971012).

Study B1971057 is a Phase 3, randomised, active-controlled, observer-blinded, multicentre trial in which subjects 10 to 25 years of age received Trumenba at months 0 and 6 (coadministered with MenACWY-CRM for the first dose) or an investigational pentavalent meningococcal vaccine at months 0 and 6. A total of 1,057 subjects received Trumenba and 543 subjects received the investigational control. The hSBA titres for primary test strains are presented in Table 1. Table 2 presents the hSBA titres against the additional 10 test strains which support and extend the breadth of vaccine coverage demonstrated by the 4 representative primary strains.

Table 1: hSBA titres among subjects 10 to 25 years of age receiving Trumenba on a 0- and 6-month schedule for primary strains 1 month post-dose 2 (Study B1971057)

	≥ 4-fold rise[1]		Titre ≥ 1:8[2]		GMT[3]	Composite[4]			
						Pre-vaccination 1		Post-dose 2	
Strain	**N**	**% (95% CI)**	**N**	**% (95% CI)**	**GMT (95% CI)**	**N**	**% (95% CI)**	**N**	**% (95% CI)**
A22	827	73.8 (70.6, 76.7)	852	91.0 (88.8, 92.8)	49.3 (46.2, 52.6)	799	1.8 (1.0, 2.9)	814	74.3 (71.2, 77.3)
A56	823	95.0 (93.3, 96.4)	854	99.4 (98.6, 99.8)	139.5 (130.6, 149.1)				
B24	835	67.4 (64.1, 70.6)	842	79.3 (76.4, 82.0)	21.2 (19.6, 22.9)				
B44	850	86.4 (83.9, 88.6)	853	94.5 (92.7, 95.9)	37.8 (35.1, 40.8)				

Abbreviations: GMT=geometric mean titre; hSBA=serum bactericidal assay using human complement.
[1] A ≥ 4-fold rise is defined as (i) A hSBA titre ≥ 1:16 for subjects with a baseline hSBA titre < 1:4. (ii) Four times the 1:8 or 16 threshold or four times the baseline hSBA titre, whichever is higher for subjects with a baseline hSBA titre ≥ 1:4.
[2] All strains used a 1:8 titre threshold except A22 which was 1:16.
[3] N for GMT is the same as that presented in preceding titre ≥ 1:8 or 16 column.
[4] Proportion of subjects with a composite of hSBA titres ≥ 1:8 or 16 for all four primary strains combined.

Table 2: hSBA titres among subjects 10 to 25 years of age receiving Trumenba on a 0- and 6-month schedule for additional strains 1 month post-dose 2 (Study B1971057)

	N	% titre ≥ 1:8[1]	95% CI
A06	159	89.3	83.4, 93.6
A07	157	96.8	92.7, 99.0
A12	157	83.4	76.7, 88.9
A15	165	89.1	83.3, 93.4
A19	167	90.4	84.9, 94.4
A29	166	95.2	90.7, 97.9
B03	164	74.4	67.0, 80.9
B09	166	71.1	63.6, 77.8
B15	167	85.0	78.7, 90.1

Table 2: hSBA titres among subjects 10 to 25 years of age receiving Trumenba on a 0- and 6-month schedule for additional strains 1 month post-dose 2 (Study B1971057)			
	N	**% titre ≥ 1:8[(1)]**	**95% CI**
B16	164	77.4	70.3, 83.6
Abbreviations: hSBA=serum bactericidal assay using human complement. [(1)] All strains used a 1:8 titre threshold except A06, A12 and A19 which were 1:16.			

Study B1971009 was a Phase 3, randomised, active-controlled, observer-blinded, multicentre trial in which subjects 10 to 18 years of age received 1 of 3 lots of Trumenba or the active control hepatitis A virus (HAV) vaccine/saline (control). A total of 2,693 subjects received at least 1 dose of Trumenba and 897 received at least 1 dose of HAV vaccine/saline. The study assessed the safety, tolerability, immunogenicity, and demonstration of manufacturability of 3 lots of Trumenba administered on a 0-, 2-, and 6-month schedule. The hSBA titres for primary test strains observed after the third dose in lot 1 and the control are presented in Table 3. Results from lots 2 and 3 are not presented, as only 2 representative strains were evaluated. Similar results were observed for lots 2 and 3 as observed for lot 1.

Study B1971016 was a Phase 3, randomised, placebo-controlled, observer-blinded, multicentre trial in which subjects 18 to 25 years of age were assigned to receive either Trumenba at months 0, 2, and 6 or saline at months 0, 2, and 6 in a 3:1 ratio. A total of 2,471 subjects received Trumenba and 822 received saline. The hSBA titres for primary test strains observed after the third dose are presented in Table 3.

Table 3. hSBA titres among subjects 10 to 25 years of age receiving Trumenba 1 month post-dose 3 of Trumenba or control on a 0-, 2-, 6-month schedule for primary strains (Study B1971009 and Study B1971016)

		Study B1971009 (10-18 years of age)				**Study B1971016 (18-25 years of age)**			
		Trumenba		**HAV/saline**		**Trumenba**		**Saline**	
Strain		**N**	**% or GMT (95% CI)**	N	**% or GMT (95% CI)**	**N**	**% or GMT (95% CI)**	**N**	**% or GMT (95% CI)**
A22	**≥ 4-fold rise[(1)]**	1225	83.2 (81.0, 85.2)	730	9.6 (7.6, 12.0)	1695	80.5 (78.6, 82.4)	568	6.3 (4.5, 8.7)
	hSBA ≥ 1:16	1266	97.8 (96.8, 98.5)	749	34.0 (30.7, 37.6)	1714	93.5 (92.2, 94.6)	577	36.6 (32.6, 40.6)
	hSBA GMT	1266	86.8 (82.3, 91.5)	749	12.6 (12.0, 13.4)	1714	74.3 (70.2, 78.6)	577	13.2 (12.4, 14.1)
A56	**≥ 4-fold rise[(1)]**	1128	90.2 (88.4, 91.9)	337	11.3 (8.1, 15.1)	1642	90.0 (88.4, 91.4)	533	10.3 (7.9, 13.2)
	hSBA ≥ 1:8	1229	99.5 (98.9, 99.8)	363	27.5 (23.0, 32.5)	1708	99.4 (98.9, 99.7)	552	34.2 (30.3, 38.4)
	hSBA GMT	1229	222.5 (210.1, 235.6)	363	8.8 (7.6, 10.1)	1708	176.7 (167.8, 186.1)	552	9.1 (8.2, 10.1)
B24	**≥ 4-fold rise[(1)]**	1235	79.8 (77.4, 82.0)	752	2.7 (1.6, 4.1)	1675	79.3 (77.3, 81.2)	562	5.5 (3.8, 7.7)
	hSBA ≥ 1:8	1250	87.1 (85.1, 88.9)	762	7.0 (5.3, 9.0)	1702	95.1 (93.9, 96.0)	573	30.2 (26.5, 34.1)
	hSBA GMT	1250	24.1 (22.7, 25.5)	762	4.5 (4.4, 4.7)	1702	49.5 (46.8, 52.4)	573	7.2 (6.6, 7.8)
B44	**≥ 4-fold rise[(1)]**	1203	85.9 (83.8, 87.8)	391	1.0 (0.3, 2.6)	1696	79.6 (77.6, 81.5)	573	1.6 (0.7, 3.0)
	hSBA ≥ 1:8	1210	89.3 (87.4, 90.9)	393	5.3 (3.3, 8.1)	1703	87.4 (85.8, 89.0)	577	11.4 (9.0, 14.3)

Table 3. hSBA titres among subjects 10 to 25 years of age receiving Trumenba 1 month post-dose 3 of Trumenba or control on a 0-, 2-, 6-month schedule for primary strains (Study B1971009 and Study B1971016)

		Study B1971009 (10-18 years of age)				Study B1971016 (18-25 years of age)			
		Trumenba		HAV/saline		Trumenba		Saline	
Strain		**N**	**% or GMT (95% CI)**	N	**% or GMT (95% CI)**	**N**	**% or GMT (95% CI)**	**N**	**% or GMT (95% CI)**
	hSBA GMT	1210	50.9 (47.0, 55.2)	393	4.4 (4.2, 4.6)	1703	47.6 (44.2, 51.3)	577	4.8 (4.6, 5.1)
Composite[2]									
Pre-vaccination 1		1088	1.1 (0.6, 1.9)	354	2.0 (0.8, 4.0)	1612	7.3 (6.0, 8.6)	541	6.1 (4.2, 8.5)
Post-dose 3		1170	83.5 (81.3, 85.6)	353	2.8 (1.4, 5.1)	1664	84.9 (83.1, 86.6)	535	7.5 (5.4, 10.0)

Abbreviations: GMT=geometric mean titre; hSBA=serum bactericidal assay using human complement; HAV=hepatitis A virus vaccine.
[1] A ≥ 4-fold rise is defined as (i) A hSBA titre ≥ 1:16 for subjects with a baseline hSBA titre < 1:4. (ii) Four times the 1:8/16 threshold or four times the baseline hSBA titre, whichever is higher for subjects with a baseline hSBA titre ≥ 1:4.
[2] Proportion of subjects with a composite of hSBA titres ≥ 1:8 or 16 for all four primary strains combined.

In Studies B1971009 and B1971016, the proportion of subjects achieving a hSBA titre ≥ 1:8 (variants A07, A15, A29, B03, B09, B15, B16) or 1:16 (variants A06, A12, A19) against the 10 additional test strains after 3 doses of Trumenba, administered on a 0-, 2-, and 6-month schedule, was determined. Across the two studies, the majority of subjects, ranging from 71.3% to 99.3% for the 6 subfamily A fHbp strains and 77.0% to 98.2% for the 4 subfamily B fHbp strains, achieved a hSBA titre ≥ 1:8 or 16, consistent with the results observed with the 4 primary test strains.

In Study B1971012, a Phase 2 study in subjects 11 to 18 years of age in Europe, hSBA titres following completion of two 3-dose schedules (0, 1, and 6 months and 0, 2, and 6 months) and a 2-dose schedule (0, 6 months) were determined against the 4 primary test strains. At 1 month after the third dose, similar robust and broad immune responses were observed for both 3-dose schedules with 86.1% to 99.4% achieving hSBA titres ≥ 1:8 or 16 and 74.6% to 94.2% achieving a 4-fold increase in hSBA titre. At 1 month after completion of the 2-dose schedule (0, 6 months), 77.5% to 98.4% achieved hSBA titres ≥ 1:8 or 16 and 65.5% to 90.4% achieved a 4-fold increase in hSBA titre.

Study B1971033 was an open-label, follow-up study of subjects previously enrolled in a primary study, including Study B1971012. Subjects attended visits over 4 years for collection of blood samples and received a single booster dose of Trumenba approximately 4 years after receipt of a primary series of 2 or 3 doses of Trumenba. hSBA titres 4 years after the primary series and 26 months after the booster dose for subjects enrolled from primary Study B1971012 Group 1 (0-, 1-, 6-Month Schedule), Group 2 (0-, 2-, 6-Month), and Group 3 (0-, 6-Month) are presented in Table 4. A booster response was observed as measured by hSBA at 1 month following a dose of Trumenba approximately 4 years after a primary series of 2 doses (Group 3) or 3 doses (Groups 1 and 2).

Table 4: hSBA titres among subjects 11 to 18 years of age receiving Trumenba on a 0-, 1-, 6-month; 0-, 2-, 6-month; and 0-, 6-month schedules and a booster 4 years after primary series completion (Study B1971033)

			Primary Study B1971012 Vaccine Groups (as Randomised)								
			0, 1, and 6 months			0, 2, and 6 months			0 and 6 months		
Strain	**Timepoint**		**N**	**% ≥ 1:8[1] (95% CI)**	**GMT (95% CI)**	**N**	**% ≥ 1:8[1] (95% CI)**	**GMT (95% CI)**	**N**	**% ≥ 1:8[1] (95% CI)**	**GMT (95% CI)**
A22	Post-primary	month 1	59	89.8 (79.2, 96.2)	53.0 (40.4, 69.6)	57	91.2 (80.7, 97.1)	59.5 (45.5, 77.8)	61	98.4 (91.2, 100.0)	55.8 (46.2, 67.4)
		month 12	99	41.4 (31.6, 51.8)	14.9 (12.6, 17.7)	111	45.0 (35.6, 54.8)	15.8 (13.4, 18.6)	113	36.3 (27.4, 45.9)	15.6 (13.0, 18.8)

Table 4: hSBA titres among subjects 11 to 18 years of age receiving Trumenba on a 0-, 1-, 6-month; 0-, 2-, 6-month; and 0-, 6-month schedules and a booster 4 years after primary series completion (Study B1971033)

Strain	Timepoint		Primary Study B1971012 Vaccine Groups (as Randomised)								
			0, 1, and 6 months			0, 2, and 6 months			0 and 6 months		
			N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)	N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)	N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)
		month 48	59	49.2 (35.9, 62.5)	16.6 (13.0, 21.1)	57	56.1 (42.4, 69.3)	20.7 (15.6, 27.4)	61	55.7 (42.4, 68.5)	16.6 (13.4, 20.5)
	Post-booster	month 1	59	100.0 (93.9, 100.0)	126.5 (102.7, 155.8)	58	100.0 (93.8, 100.0)	176.7 (137.8, 226.7)	60	96.7 (88.5, 99.6)	142.0 (102.9, 196.1)
	Post-booster	month 12	58	74.1 (61.0, 84.7)	33.6 (24.5, 46.1)	54	77.8 (64.4, 88.0)	44.1 (31.2, 62.4)	60	80.0 (67.7, 89.2)	31.6 (23.5, 42.5)
	Post-booster	month 26	0	NE[2]	NE[2]	34	73.5 (55.6, 87.1)	34.7 (23.0, 52.4)	42	61.9 (45.6, 76.4)	27.1 (18.6, 39.6)
A56	Post-primary	month 1	58	100.0 (93.8, 100.0)	158.7 (121.5, 207.3)	57	98.2 (90.6, 100.0)	191.2 (145.8, 250.8)	62	98.4 (91.3, 100.0)	143.1 (109.6, 187.0)
	Post-primary	month 12	98	73.5 (63.6, 81.9)	25.7 (19.4, 34.0)	109	76.1 (67.0, 83.8)	27.3 (21.0, 35.4)	106	60.4 (50.4, 69.7)	18.5 (13.8, 24.7)
	Post-primary	month 48	53	43.4 (29.8, 57.7)	10.7 (7.4, 15.3)	55	56.4 (42.3, 69.7)	15.0 (10.2, 22.2)	62	43.5 (31.0, 56.7)	10.8 (7.6, 15.3)
	Post-booster	month 1	57	100.0 (93.7, 100.0)	359.8 (278.7, 464.7)	56	100.0 (93.6, 100.0)	414.8 (298.8, 575.9)	62	98.4 (91.3, 100.0)	313.1 (221.3, 442.8)
	Post-booster	month 12	55	90.9 (80.0, 97.0)	47.3 (34.3, 65.3)	55	89.1 (77.8, 95.9)	64.0 (42.6, 96.2)	59	81.4 (69.1, 90.3)	41.0 (26.7, 62.7)
	Post-booster	month 26	0	NE[2]	NE[2]	29	82.8 (64.2, 94.2)	37.8 (21.3, 67.2)	40	57.5 (40.9, 73.0)	16.0 (9.9, 25.8)
B24	Post-primary	month 1	59	88.1 (77.1, 95.1)	25.6 (19.7, 33.3)	58	91.4 (81.0, 97.1)	30.5 (23.8, 39.1)	60	85.0 (73.4, 92.9)	29.2 (21.5, 39.6)
	Post-primary	month 12	98	40.8 (31.0, 51.2)	9.7 (7.5, 12.4)	108	49.1 (39.3, 58.9)	11.5 (9.0, 14.6)	103	36.9 (27.6, 47.0)	8.4 (6.7, 10.6)
	Post-primary	month 48	59	40.7 (28.1, 54.3)	10.7 (7.6, 15.1)	57	49.1 (35.6, 62.7)	11.4 (8.2, 15.9)	62	40.3 (28.1, 53.6)	8.9 (6.8, 11.8)
	Post-booster	month 1	58	100.0 (93.8, 100.0)	94.9 (74.6, 120.9)	57	100.0 (93.7, 100.0)	101.6 (83.1, 124.2)	62	96.8 (88.8, 99.6)	79.1 (60.6, 103.5)
	Post-booster	month 12	58	65.5 (51.9, 77.5)	21.1 (14.2, 31.3)	54	74.1 (60.3, 85.0)	25.7 (17.7, 37.5)	62	77.4 (65.0, 87.1)	22.4 (16.4, 30.5)
	Post-booster	month 26	0	NE[2]	NE[2]	33	78.8 (61.1, 91.0)	24.4 (16.1, 36.8)	42	59.5 (43.3, 74.4)	14.5 (9.9, 21.3)
B44	Post-primary	month 1	58	86.2 (74.6, 93.9)	46.3 (31.7, 67.8)	57	89.5 (78.5, 96.0)	50.2 (35.3, 71.3)	60	81.7 (69.6, 90.5)	35.5 (24.5, 51.4)
	Post-primary	month 12	100	24.0 (16.0, 33.6)	6.4 (5.2, 7.8)	111	22.5 (15.1, 31.4)	6.0 (5.1, 7.2)	115	16.5 (10.3, 24.6)	5.6 (4.8, 6.5)
	Post-primary	month 48	57	36.8 (24.4, 50.7)	8.3 (6.3, 11.0)	57	35.1 (22.9, 48.9)	7.6 (5.8, 10.0)	62	12.9 (5.7, 23.9)	4.6 (4.1, 5.1)
	Post-booster	month 1	59	100.0 (93.9, 100.0)	137.3 (100.3, 188.0)	58	100.0 (93.8, 100.0)	135.9 (108.0, 171.0)	61	93.4 (84.1, 98.2)	74.2 (51.6, 106.8)
	Post-booster	month 12	56	75.0 (61.6, 85.6)	23.2 (16.2, 33.2)	53	81.1 (68.0, 90.6)	24.3 (17.8, 33.3)	61	59.0 (45.7, 71.4)	13.3 (9.7, 18.3)
	Post-booster	month 26	0	NE[2]	NE[2]	33	66.7 (48.2, 82.0)	16.0 (10.4, 24.7)	43	62.8 (46.7, 77.0)	13.6 (9.8, 18.9)
Composite[3]											
	Post-	month 1	57	80.7 (68.1, 90.0)	NE	55	87.3 (75.5, 94.7)	NE	57	77.2 (64.2, 87.3)	NE

Table 4: hSBA titres among subjects 11 to 18 years of age receiving Trumenba on a 0-, 1-, 6-month; 0-, 2-, 6-month; and 0-, 6-month schedules and a booster 4 years after primary series completion (Study B1971033)

Strain	Timepoint		Primary Study B1971012 Vaccine Groups (as Randomised)								
			0, 1, and 6 months			0, 2, and 6 months			0 and 6 months		
			N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)	N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)	N	% ≥ 1:8[1] (95% CI)	GMT (95% CI)
		month 12	55	10.9 (4.1, 22.2)	NE	51	13.7 (5.7, 26.3)	NE	49	20.4 (10.2, 34.3)	NE
		month 48	51	19.6 (9.8, 33.1)	NE	53	30.2 (18.3, 44.3)	NE	61	9.8 (3.7, 20.2)	NE
	Post-booster	month 1	56	100 (93.6, 100.0)	NE	55	100.0 (93.5, 100.0)	NE	59	91.5 (81.3, 97.2)	NE
	Post-booster	month 12	53	52.8 (38.6, 66.7)	NE	48	64.6 (49.5, 77.8)	NE	57	61.4 (47.6, 74.0)	NE
	Post-booster	month 26	0	NE[2]	NE	27	48.1 (28.7, 68.1)	NE	36	44.4 (27.9, 61.9)	NE

Abbreviations: hSBA=serum bactericidal assay using human complement; NE=not evaluated; GMT=geometric mean titre.
[1] All strains used a 1:8 titre threshold except A22 which was 1:16.
[2] Subjects were not followed beyond 12 months post booster.
[3] Proportion of subjects with a composite of hSBA titres ≥ 1:8 or 16 for all four primary strains combined.
Serum samples were analysed concurrently in the same serology campaign for all time points except the 12 months post-primary dose time point for which results are from the interim analysis.

Immunogenicity in individuals 1 to 9 years of age

The immunogenicity of Trumenba (0-, 2-, 6-month schedule) in toddlers and children 1 to 9 years of age was evaluated in 2 Phase 2 studies. At 1 month following series completion, 81.4% to 100% of subjects achieved a response to the 4 primary meningococcal test strains (defined as hSBA ≥ 1:16 for A22; ≥ 1:8 for A56, B24 and B44) compared to 0.4% to 6.5% at baseline.

There are no persistence data in children 1 to < 2 years of age. In children 2 to 9 years of age, 6 months following series completion, 32.5%, 82.4%, 15.5% and 10.4% of participants maintained a response to the primary test strains A22, A56, B24 and B44, respectively. See section 4.2 for information on use in children 1 to 9 years of age.

The European Medicines Agency has deferred the obligation to submit the results of studies with Trumenba in one or more subsets of the paediatric population for prevention of invasive meningococcal disease caused by *N. meningitidis* serogroup B (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of repeated dose toxicity and reproduction and developmental toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Histidine

Polysorbate 80 (E433)
Water for injections
For adsorbent, see section 2.

6.2 Incompatibilities

Do not mix Trumenba with other vaccines or medicinal products in the same syringe.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store in a refrigerator (2 °C-8 °C).
Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.
Do not freeze.

6.5 Nature and contents of container

0.5 ml suspension in a pre-filled syringe (Type I glass) with plastic Luer Lok adapter, chlorobutyl rubber plunger stopper, and a synthetic isoprene bromobutyl rubber tip cap with a plastic rigid tip cap cover with or without needle. The tip cap and rubber plunger of the pre-filled syringe are not made with natural rubber latex.

Pack sizes of 1, 5, and 10 pre-filled syringes, with or without needle.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

During storage, a white deposit and clear supernatant may be observed in the pre-filled syringe containing the suspension.

Before use, the pre-filled syringe should be shaken vigorously to ensure that a homogeneous white suspension is obtained.

Do not use the vaccine if it cannot be re-suspended.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1187/001
EU/1/17/1187/002
EU/1/17/1187/003
EU/1/17/1187/004
EU/1/17/1187/005
EU/1/17/1187/006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th May 2017

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

Boehringer Ingelheim RCV GmbH & Co KG (BI RCV)
Dr. Boehringer Gasse 5-11
A-1121 Vienna
Austria

Or

Pfizer Health AB
Mariefredsvägen 37
S-645 41 Strängnäs
Sweden

Name and address of the manufacturer responsible for batch release

Pfizer Manufacturing Belgium N.V.
Rijksweg 12
B-2870 Puurs
Belgium

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer Carton Pack of 1, 5 or 10 pre-filled syringes; with or without needles

1. NAME OF THE MEDICINAL PRODUCT

Trumenba suspension for injection in pre-filled syringe
meningococcal group B vaccine (recombinant, adsorbed)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 dose (0.5 ml) contains:

Neisseria meningitidis serogroup B fHbp subfamily A and B 60 micrograms each

3. LIST OF EXCIPIENTS

Sodium chloride, histidine, water for injections, aluminium phosphate and polysorbate 80 (E433).

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
1 single-dose (0.5 ml) pre-filled syringe with needle
1 single-dose (0.5 ml) pre-filled syringe without needle
5 single-dose (0.5 ml) pre-filled syringes with needles
5 single-dose (0.5 ml) pre-filled syringes without needles
10 single-dose (0.5 ml) pre-filled syringes with needles
10 single-dose (0.5 ml) pre-filled syringes without needles

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Shake well before use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.
Do not freeze.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1187/001 – pack of 1 with separate needle
EU/1/17/1187/002 – pack of 1 without needle
EU/1/17/1187/003 – pack of 5 with separate needles
EU/1/17/1187/004 – pack of 5 without needles
EU/1/17/1187/005 – pack of 10 with separate needles
EU/1/17/1187/006 – pack of 10 without needles

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pre-filled syringe label

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Trumenba suspension for injection
meningococcal B vaccine
IM

2. METHOD OF ADMINISTRATION

Shake well before use.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose (0.5 ml)

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Trumenba suspension for injection in pre-filled syringe
meningococcal group B vaccine
(recombinant, adsorbed)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you or your child

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trumenba is and what it is used for

Trumenba is a vaccine to prevent invasive meningococcal disease, caused by *Neisseria meningitidis* serogroup B, for use in people 10 years and older. This is a type of bacteria that can cause serious and sometimes life threatening infections such as meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning).

The vaccine contains 2 important components from the surface of the bacteria.

The vaccine works by helping the body to make antibodies (the body's natural defences) which protect you or your child against this disease.

2. What you need to know before you or your child receives Trumenba

Trumenba should not be given
- if you or your child are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination with Trumenba. Tell your doctor, pharmacist or nurse if you or your child:
- have a severe infection with a high fever. If this is the case, then vaccination will be postponed. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but talk to your doctor first.
- have a bleeding problem or bruise easily.

- have a weakened immune system which may prevent you or your child from getting the full benefit from Trumenba.
- have had any problems after any dose of Trumenba such as an allergic reaction or problems with breathing.

Fainting, feeling faint, or other stress-related reactions can occur as a response to any needle injection. Tell your doctor, pharmacist or nurse if you have experienced this kind of reaction previously.

Other medicines and Trumenba
Tell your doctor, pharmacist or nurse if you or your child are using, have recently used or might use any other medicines or have recently received any other vaccine.

Trumenba can be given at the same time as any of the following vaccine components: tetanus, diphtheria, whooping cough (pertussis), poliovirus, papillomavirus, and meningococcal serogroups A, C, W, Y.

Administration of Trumenba with vaccines other than those mentioned above, has not been studied.

If you receive more than 1 vaccination at the same time it is important that different injection sites are used.

If you take medicines that affect your immune system (such as radiation therapy, corticosteroids, or some types of cancer chemotherapies), you may not get the full benefit of Trumenba.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before Trumenba is given. Your doctor may still recommend that you receive Trumenba if you are at risk of meningococcal disease.

Driving and using machines
Trumenba has no or little influence on the ability to drive and use machines.

However, some of the side effects mentioned under section 4 'Possible side effects' may temporarily affect you. If this occurs, wait until the effects wear off before driving or using machines.

Trumenba contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Trumenba is given

Trumenba will be given to you or your child by a doctor, pharmacist or nurse. It will be injected into the upper arm muscle.

It is important to follow the instructions from the doctor, pharmacist or nurse so that you or your child completes the course of injections.

Individuals 10 years and older
- You or your child will receive 2 injections of the vaccine, the second injection is given 6 months after the first injection;
  or
- You or your child will receive 2 injections of the vaccine given at least 1 month apart and a third injection at least 4 months after the second injection.
- You or your child may be given a booster.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

When Trumenba is given to your or your child, the following side effects may occur:

Very common (may affect more than 1 in 10 people)
- Redness, swelling and pain at injection site
- Headache
- Diarrhoea
- Nausea
- Muscle pain
- Joint pain
- Chills
- Fatigue

Common (may affect up to 1 in 10 people)
- Vomiting
- Fever ≥38 °C

Not known (frequency cannot be estimated from the available data)
- Allergic reactions

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trumenba

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C-8 °C).

Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.

Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trumenba contains

One dose (0.5 ml) contains:

Active substances:

Neisseria meningitidis serogroup B fHbp subfamily A[1,2,3]	60 micrograms
Neisseria meningitidis serogroup B fHbp subfamily B[1,2,3]	60 micrograms

[1] Recombinant lipidated fHbp (factor H binding protein)
[2] Produced in *Escherichia coli* cells by recombinant DNA technology
[3] Adsorbed on aluminium phosphate (0.25 milligram aluminium per dose)

Other ingredients:

Sodium chloride (see section 2 **Trumenba contains sodium**), histidine, water for injections, and polysorbate 80 (E433).

What Trumenba looks like and contents of the pack

Trumenba is a white suspension for injection, provided in a pre-filled syringe.

Pack sizes of 1, 5, and 10 pre-filled syringes with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:	Manufacturer responsible for batch release:
Pfizer Europe MA EEIG Boulevard de la Plaine 17 1050 Bruxelles Belgium	Pfizer Manufacturing Belgium N.V. Rijksweg 12 B-2870 Puurs Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

During storage, a white deposit and clear supernatant may be observed.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

Shake well prior to use to obtain a homogeneous white suspension.

Trumenba is for intramuscular use only. Do not administer intravascularly or subcutaneously.

Trumenba must not be mixed with any other vaccines in the same syringe.

When given at the same time with other vaccines Trumenba must be given at separate injection sites.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.