Approval Date: March 14, 2018

Product: TRUMENBA

Proper Name: Meningococcal Group B Vaccine

Manufacturer: Wyeth Pharmaceuticals, Inc.

Indication: Indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba is approved for use in individuals 10 through 25 years of age.

Description: Trumenba is a sterile suspension composed of two recombinant lipidated factor H binding protein (fHBP) variants from N. meningitidis serogroup B, one from fHBP subfamily A and one from subfamily B (A05 and B01, respectively).

BLA: BL 125549

Regulatory Milestone:

On June 16, 2014, Wyeth Pharmaceuticals, Inc. (U.S. license 0003), a subsidiary of Pfizer Inc., submitted BLA 125549 for licensure of Meningococcal Group B Vaccine (Trumenba). Trumenba was approved on October 29, 2014, under the accelerated approval regulations (21 CFR 601.4o-46) for active immunization to prevent invasive disease caused by N. meningitidis serogroup B in individuals 10 through 25 years of age. On March 27, 2015, the Applicant submitted a Clinical Efficacy Supplement (STN 125549/17) to revise the dosing regimen. The FDA approved the supplement on April 14, 2016, to include a two-dose schedule (a dose administered at 0 and 6 months) under the regulations for accelerated approval, 21 CFR 601.40-46. The approval also included a modification of the three-dose schedule (that had been approved

under the original BLA according to the regulations for accelerated approval) from administration at 0, 2, and 6 months to administration at 0, 1-2, and 6 months.

PDUFA Goal Date: March 13, 2017

Package Insert: Package Insert - TRUMENBA

Summary Basis for Regulatory Approval: March 13, 2017 Summary Basis for Regulatory Action - Trumenba

European Public Assessment Report: Human medicine European public assessment report (EPAR): Trumenba

Advisory Committee:

A Vaccines and Related Biologics Products Advisory Committee meeting was not held, as there were no issues or concerns that presented during the course of review of the supplement that required consult from the advisory committee.

NCT Numbers:

- NCT02569632
- NCT04295733
- NCT02106390
- NCT00937521
- NCT04415424
- NCT04350138
- NCT02212457
- NCT00443157
- NCT03089086
- NCT02398396
- NCT04318548
- NCT00847145
- NCT03682939
- NCT01894919
- NCT04166656
- NCT00798304
- NCT02173704
- NCT04094883
- NCT01478347
- NCT03135834
- NCT02583412
- NCT00962624
- NCT04297436
- NCT03621670
- NCT03125616
- NCT04239430
- NCT04084769
- NCT00657709
- NCT03509051
- NCT04597424
- NCT04398849
- NCT00944034

- NCT00433914
- NCT00661713
- NCT00560313
- NCT00780806
- NCT00721396
- NCT03493919
- NCT03632720
- NCT00808028
- NCT02712177
- NCT01139021
- NCT04440163
- NCT01717638
- NCT02491463
- NCT02141516
- NCT01423084
- NCT01911221
- NCT01339923
- NCT01214850
- NCT01973218
- NCT00381615
- NCT02305446
- NCT00879814
- NCT02534935
- NCT00297687
- NCT02868970
- NCT02482636
- NCT02946385
- NCT02640677
- NCT04502693
- NCT03587207
- NCT02080559
- NCT00197795
- NCT00297817
- NCT02446743
- NCT00137917
- NCT04645966
- NCT04707391
- NCT04023929
- NCT02975596
- NCT03636906
- NCT04515368
- NCT02451514
- NCT03419533

EudraCT Numbers:

- 2011-004400-38
- 2008-004765-26
- 2008-007789-51
- 2007-000304-32
- 2008-001457-18

Publications:

- Vesikari, T., Østergaard, L., Diez-Domingo, J., Wysocki, J., Flodmark, C. E., Beeslaar, J., Eiden, J., Jiang, Q., Jansen, K. U., Jones, T. R., Harris, S. L., O'Neill, R. E., York, L. J., Crowther, G., & Perez, J. L. (2016). Meningococcal Serogroup B Bivalent rLP2086 Vaccine Elicits Broad and Robust Serum Bactericidal Responses in Healthy Adolescents. *Journal of the Pediatric Infectious Diseases Society*, *5*(2), 152–160. https://doi.org/10.1093/jpids/piv039
- Vesikari, T., Wysocki, J., Beeslaar, J., Eiden, J., Jiang, Q., Jansen, K. U., Jones, T. R., Harris, S. L., O'Neill, R. E., York, L. J., & Perez, J. L. (2016). Immunogenicity, Safety, and Tolerability of Bivalent rLP2086 Meningococcal Group B Vaccine Administered Concomitantly With Diphtheria, Tetanus, and Acellular Pertussis and Inactivated

Poliomyelitis Vaccines to Healthy Adolescents. *Journal of the Pediatric Infectious Diseases Society*, *5*(2), 180–187. https://doi.org/10.1093/jpids/piv064

- Ostergaard, L., Lucksinger, G. H., Absalon, J., Beeslaar, J., Eiden, J., Jansen, K. U., York, L. J., Quinn, A., Graversen, M. E., & Perez, J. L. (2016). A phase 3, randomized, active-controlled study to assess the safety and tolerability of meningococcal serogroup B vaccine bivalent rLP2086 in healthy adolescents and young adults. *Vaccine*, *34*(12), 1465–1471. https://doi.org/10.1016/j.vaccine.2016.01.044