EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/152667/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Trumenba

Meningococcal group B vaccine (recombinant, adsorbed)

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trumenba, intended for prophylaxis against invasive meningococcal disease caused by meningococcal serogroup B bacteria. The applicant for this medicinal product is Pfizer Limited.

Trumenba will be available as a suspension for injection. The active substances of Trumenba are two recombinant lipidated factor H binding protein (fHbp) variants from subfamily A and B, which are found on the surface of *Neisseria meningitidis* serogroup B (ATC code: J07AH09). Immunisation with Trumenba is intended to stimulate the production of bactericidal antibodies that recognize fHbp expressed by meningococci.

The benefits with Trumenba are its ability to induce protective serum bactericidal antibody responses to a number of meningococcal serogroup B test strains expressing fHbp variants that are representative of meningococcal serogroup B strains causing invasive disease. The most common side effects are injection site local reactions (pain, redness and swelling), headache, fatigue, chills, diarrhoea, muscle and joint pain, and nausea.

The full indication is: "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".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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