EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2020
EMA/CHMP/460994/2020
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Obiltoxaximab SFL

obiltoxaximab



On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Obiltoxaximab SFL[3], intended for the treatment or post-exposure prophylaxis of inhalational anthrax. The applicant for this medicinal product is SFL Pharmaceuticals Deutschland GmbH.

Obiltoxaximab SFL will be available as 100 mg/ml concentrate for solution for infusion. The active substance of Obiltoxaximab SFL is obiltoxaximab (ATC code: J06BB22), a monoclonal antibody that binds to the protective antigen (PA) of *Bacillus anthracis* toxin. Obiltoxaximab thereby inhibits the binding of PA to its cellular receptors, preventing the intracellular entry of the toxin components responsible for the pathogenic effects of anthrax toxin.

The benefits with Obiltoxaximab SFL are its ability to neutralise the PA component of anthrax toxin, which led to increased survival in animal challenge studies. The most common side effects in healthy human volunteers receiving obiltoxaximab are headache, pruritus, and urticaria. Hypersensitivity reactions (including rash) occurred in approximately 10% of exposed subjects and anaphylaxis occurred in <1% of exposed subjects. The safety of obiltoxaximab has been studied only in healthy volunteers.

The full indication is:

> Obiltoxaximab SFL is indicated in combination with appropriate antibacterial drugs in all age groups for treatment of inhalational anthrax due to *Bacillus anthracis* (see section 5.1).

[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
[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Obiltoxaximab SFL is indicated in all age groups for post-exposure prophylaxis of inhalational anthrax when alternative therapies are not appropriate or are not available (see section 5.1).

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.