EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2019
EMA/CHMP/213223/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Libtayo

cemiplimab

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Libtayo, intended for the treatment of advanced cutaneous squamous cell carcinoma. The applicant for this medicinal product is Regeneron Ireland U.C.

Libtayo will be available as a 350 mg concentrate for solution for infusion. The active substance of Libtayo is cemiplimab, an antineoplastic agent that binds to the programmed cell death-1 (PD-1) receptor and blocks its interaction with its ligands PD-L1 and PD-L2.

The benefits with Libtayo are its ability to reduce tumour size and to prevent progression of the tumour for longer compared to historical controls from the literature in adult patients with locally advanced or metastatic cutaneous squamous cell carcinoma. The most common side effects are rash, fatigue, diarrhoea and pruritus. The most common immune-related side effects are hypothyroidism, pneumonitis, skin adverse reactions, hyperthyroidism and hepatitis.

The full indication is: "Libtayo as monotherapy is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation".

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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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