24 June 2021
EMA/CHMP/314017/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Minjuvi

tafasitamab

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation[2] for the medicinal product Minjuvi,[3] intended for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem-cell transplant (ASCT).

The applicant for this medicinal product is Incyte Biosciences Distribution B.V.

Minjuvi will be available as a powder for concentrate for solution for infusion (200 mg). The active substance of Minjuvi is tafasitamab, a monoclonal antibody (ATC code: L01FX12) that targets the CD19 antigen expressed on the surface of pre-B and mature B lymphocytes. Upon binding to CD19, tafasitamab mediates B-cell lysis through effector cells of the immune system, such as natural killer cells, gammadelta T cells and phagocytes, and direct induction of cell death (apoptosis).

The benefits of Minjuvi are its objective response rate (ORR), defined as the proportion of complete and partial responders and its duration of response. The most common side effects are infections, neutropenia (including febrile neutropenia), thrombocytopenia, anaemia, leukopenia, hypokalaemia, decreased appetite dyspnoea, cough, diarrhoea, constipation, vomiting, nausea, abdominal pain, rash, asthenia, fatigue, oedema peripheral and pyrexia.

The full indication is:

> Minjuvi is indicated in combination with lenalidomide followed by Minjuvi monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

[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 expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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Minjuvi should be prescribed by physicians experienced in the treatment of cancer.

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.