EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2020
EMA/CHMP/105780/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sarclisa

isatuximab

On 26 March 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sarclisa[2], intended for the treatment of multiple myeloma. The applicant for this medicinal product is sanofi-aventis groupe.

Sarclisa will be available as 20 mg/ml concentrate for solution for infusion. The active substance of Sarclisa is isatuximab, an IgG1-derived monoclonal antibody (ATC code: L01XC38) that binds to a specific extracellular epitope of CD38 receptor resulting in cancer cell death. CD38 is a transmembrane glycoprotein that is highly expressed on multiple myeloma cells.

The benefits with Sarclisa are its ability to improve progression free survival (PFS) represented by a 40.4% reduction in the risk of disease progression or death. The most common side effects are neutropenia), infusion reactions, pneumonia, upper respiratory tract infection, diarrhoea and bronchitis.

The full indication is:

"Sarclisa is indicated, in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI) and have demonstrated disease progression on the last therapy."

Sarclisa should be administered by a healthcare professional, in an environment where resuscitation facilities are available.

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] 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