25 July 2024
EMA/CHMP/318981/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vyloy

zolbetuximab

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vyloy[2], intended for the treatment of gastric or gastro-oesophageal junction (GEJ) adenocarcinoma.

The applicant for this medicinal product is Astellas Pharma Europe B.V.

Vyloy will be available as 100 mg powder for concentrate for solution for infusion. The active substance of Vyloy is zolbetuximab, an antineoplastic agent (ATC code: L01FX31). Zolbetuximab is a chimeric (mouse/human) IgG1 antibody directed against the tight junction molecule CLDN18.2, a tissue specific cell surface molecule that is expressed in normal gastric tissue as well as in many human cancers.

The benefit of Vyloy is an improved progression-free survival (PFS) in patients with locally advanced, unresectable or metastatic, HER2-negative, gastric or GEJ adenocarcinoma whose cancer was CLDN18.2-positive, as shown in two studies that evaluated zolbetuximab in combination with fluoropyrimidine- and platinum-containing chemotherapy as first-line treatment.

The most common side effects with Vyloy are nausea, vomiting, decreased appetite, neutropenia, neutrophil count decreased, weight loss, pyrexia, hypoalbuminaemia, oedema peripheral, hypertension, dyspepsia, chills, salivary hypersecretion, infusion related reaction and drug hypersensitivity.

The full indication is:

> Vyloy, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive (see section 4.2).

Treatment with Vyloy should be prescribed and supervised by physicians experienced in the treatment of cancer.

[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 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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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.