



17 December 2015
EMA/CHMP/756429/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Portrazza necitumumab

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Portrazza, intended for the treatment of epidermal growth factor receptor (EGFR)-expressing squamous non-small cell lung cancer. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Portrazza will be available as a 800-mg concentrate for solution for infusion. The active substance of Portrazza is necitumumab, a recombinant human IgG1 monoclonal antibody (ATC code: L01XC22) that binds with high affinity and specificity to the human EGFR and blocks the ligand binding site.

The benefits with Portrazza are its ability to improve survival compared with chemotherapy alone. The most common side effects are skin reactions, venous thromboembolic events and laboratory abnormalities (hypomagnesaemia and albumin-corrected hypocalcaemia).

The full indication is: "Portrazza in combination with gemcitabine and cisplatin chemotherapy is indicated for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing squamous non-small cell lung cancer who have not received prior chemotherapy for this condition". Portrazza must be administered under the supervision of a physician qualified in the use of anti-cancer chemotherapy.

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

