



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Caprelsa vandetanib

On 17 November 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Caprelsa, 100 mg, 300 mg, film-coated tablets intended for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.

The applicant for this medicinal product is AstraZeneca AB. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Caprelsa is vandetanib, a protein kinase inhibitor (L01XE) with activity against the rearranged during transfection (RET) proto-oncogene, the vascular endothelial growth factor receptor (VEGFR) and epidermal growth factor receptor (EGFR).

The benefit with Caprelsa is its ability to improve progression-free survival (PFS) as compared to placebo in patients with unresectable locally advanced or metastatic MTC.

The most common side effects are nasopharyngitis, bronchitis, upper respiratory tract infections, urinary tract infections, decreased appetite, hypocalcaemia, insomnia, depression, headache, paresthesia, dysaesthesia, dizziness, blurred vision, corneal structural change (including corneal deposits and corneal opacity), prolongation of QT interval, hypertension, abdominal pain, diarrhoea, nausea, vomiting, dyspepsia, photosensitivity reactions, rash and other skin reactions (including acne, dry skin, dermatitis, pruritis), nail disorders, proteinuria, nephrolithiasis, asthenia, fatigue, pain and oedema.

A pharmacovigilance plan for Caprelsa will be implemented as part of the marketing authorisation.

The approved indication is: "Caprelsa is indicated for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. For patients in whom rearranged during transfection (RET) mutation is not known or is negative, a

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.



possible lower benefit should be taken into account before individual treatment decision (see important information in sections 4.4 and 5.1). It is proposed that Caprelsa be prescribed by physicians experienced in treatment of medullary thyroid cancer, the use of anticancer therapies and the assessment of electrocardiogram.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Caprelsa and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional.