19 December 2013
EMA/CHMP/539526/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Cometriq

cabozantinib

On 19 December 2013 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 Cometriq 20 mg and 80 mg hard capsules, intended for the treatment of medullary thyroid cancer, a rare type of thyroid cancer, that cannot be removed by surgery or that has spread to other parts of the body.

Cometriq was designated as an orphan medicinal product on 26 February 2009.

The applicant for this medicinal product is TMC Pharma Services Ltd. 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 Cometriq is cabozantinib, an antineoplastic agent, protein kinase inhibitor. Cabozantinib inhibits multiple receptor tyrosine kinases (RTKs) implicated in tumour growth and angiogenesis, pathologic bone remodeling, and metastatic progression of cancer. By inhibiting RTKs, cabozantinib may slow or stop the growth of medullary thyroid cancer.

The benefits with Cometriq are its ability to improve progression-free survival (PFS) as compared to placebo in patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma. The most common side effects are diarrhoea, palmar-plantar erythrodysaesthesia syndrome (PPES), decreased weight, decreased appetite, nausea, fatigue, dysgeusia, hair colour changes, hypertension, stomatitis, constipation, vomiting, mucosal inflammation, asthenia and dysphonia. The most common laboratory abnormalities were increased AST, increased ALT, increased ALP, lymphopenia, hypocalcaemia, hypophosphataemia, hyperbilirubinaemia, neutropenia, thrombocytopenia and hypoalbuminaemia.

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

The approved indication is: "Cometriq is indicated for the treatment of adult patients with progressive, unresectable locally advanced or metastatic medullary thyroid carcinoma.

[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.

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For patients in whom Rearranged during Transfection (RET) mutation status is not known or is negative, a 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 Cometriq be prescribed by physicians experienced in the administration of anticancer medicinal products.

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 Cometriq and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[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 likely to provide comprehensive clinical data at a later stage.