



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Vargatef nintedanib

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vargatef, 100 and 150 mg, soft capsules intended for the treatment of locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy - in combination with docetaxel.

The applicant for this medicinal product is Boehringer Ingelheim International GmbH. 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 Vargatef is nintedanib, a tyrosine kinase inhibitor anti-neoplastic agent blocking vascular endothelial growth factor receptors (VEGFR 1-3), platelet-derived growth factor receptors (PDGFR α and β) and fibroblast growth factor receptors (FGFR 1-3) kinase activity crucial for the proliferation and survival of endothelial as well as perivascular cells, and eventually inhibiting tumour angiogenesis.

The benefits with the addition of nintedanib to docetaxel were in terms of an improvement in progression – free survival and Overall survival as compared to docetaxel plus placebo.

The most common side effects are: neutropenia (including febrile neutropenia), decreased appetite, electrolyte imbalance, peripheral neuropathy, bleeding, diarrhoea, vomiting, nausea, alanine aminotransferase increased, aspartase aminotransferase increased, blood alkaline phosphatase increased, mucositis (including stomatitis), rash.

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

The approved indication is: "Vargatef is indicated in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy." It is proposed that Vargatef be prescribed by physicians experienced in the treatment of non-small cell lung 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.



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 Vargatef and therefore recommends the granting of the marketing authorisation.