EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2019
EMA/CHMP/601091/2019
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): nintedanib (oncology indications)

Procedure No. EMEA/H/C/PSUSA/00010318/201810

Period covered by the PSUR: 15 October 2017 to 15 October 2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for nintedanib (oncology indications), the scientific conclusions of CHMP are as follows:

Venous thromboembolic events are an important identified risk with Vargatef. 'Pulmonary embolism' reported events (cumulative and interval) comprise 72% of those. In a number of cases of pulmonary embolism reported with Vargatef and although in the majority of them there were alternative risk factors, the role of Vargatef could not be excluded. As a result, a relevant update of the Product Information, also taking into consideration the role of the risk factors, is warranted.

Available data on Colitis were not considered adequate in the current assessment for Vargatef as they were not conclusive. Nevertheless, the evidence for nintedanib in the respiratory indication was considered adequate and PRAC considered that since a possible link between all three signalling pathways (PDGF, FGF and VEGF) and colitis can be hypothesized through their effect on angiogenesis, the same mechanism can also apply for the oncology indication and thus a product information update in relation to Colitis is also recommended for Vargatef.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for nintedanib (oncology indications) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nintedanib (oncology indications) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.