15 December 2016
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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/00010318/201605

Period covered by the PSUR: 22 Nov 2015 to 21 May 2016

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Scientific conclusions

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

As part of Ofev PSUSA/00010319/201510, pancreatitis was added as a new adverse drug reaction. Taking into account that nintedanib is authorised for the treatment of idiopathic pulmonary fibrosis (IPF) but also for the treatment of non-small cell lung carcinoma (NSCLC), that a higher dose of nintedanib is used for the treatment of NSCLC as compared to IPF and that post-marketing exposure was 10-fold lower for NSCLC than for IPF, data from the nintedanib oncology indications have been reviewed. The impact of the data in IPF patients on the oncology indications has also been assessed. Pancreatitis has been reported infrequently in the oncology development programme. 4 cases (3 from clinical trials and 1 from compassionate use) have been reported in the MAH's safety database and in addition 5 cases from on-going studies have been retrieved.

Considering the association of pancreatitis with nintedanib treatment in patients with IPF, that pancreatitis is a potentially serious clinical condition, that a higher dose of nintedanib is used in Vargatef together with the potential seriousness of pancreatitis if not diagnosed early enough to allow fast treatment initiation, there is no plausible medical explanation why pancreatitis as a potential side effect would be confined to only the IPF indication. Based on the available evidence, the PRAC considered that pancreatitis should be added to section 4.8 of the SmPC.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing nintedanib (oncology indications) were warranted.

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 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 should be varied.

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