13 October 2016
EMA/879483/2016
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): fingolimod

Procedure No. EMEA/H/C/PSUSA/00001393/201602

Period covered by the PSUR: 01 March 2015 to 28 February 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

## Scientific conclusions

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

305 cases of thrombocytopenia (180 serious and 125 non serious) were reported cumulatively and 80 cases (41 serious and 39 non serious) during the reporting interval. Among the 180 serious cases of thrombocytopenia cumulatively the MAH identified 31 Grade 4 among the cases where laboratory value is reported. 24 cases of positive dechallenge were reported cumulatively including 5 new cases in this PSUR period. 4 cases of rechallenge were reported cumulatively.

3 cases of Kaposi's sarcoma were reported cumulatively 16 months, 15 months and 3.5 years after the start of fingolimod. Another case was also reported following the literature assessment after the Data Lock Point of this PSUR on fingolimod treatment. All the 4 cases were biopsy confirmed and occurred > 1 year (16 months, 15 months, 3.5 years and 4 years) after the start of fingolimod, with no history of immunosuppressive agent, HIV negative serology. In those 4 cases there are no other aetiology reported to explain Kaposi's sarcoma except fingolimod exposure. Even if the time to onset is short, the chronology is compatible with a relationship between Kaposi's sarcoma and fingolimod treatment. It is important to consider that healthcare professionals should have this information to correctly monitor their patient on fingolimod therapy. 4 cases of Kaposi's sarcoma represent already a signal and Kaposi's sarcoma should be added to 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 fingolimod 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 fingolimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fingolimod 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.