EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/561914/2019
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): vismodegib

Procedure No. EMEA/H/C/PSUSA/00010140/201901

Period covered by the PSUR: 29 January 2018 to 29 January 2019

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Scientific conclusions

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

Seven cases of severe cutaneous adverse reactions (SCARs) have been reported in association with vismodegib cumulatively. At least one case of Stevens-Johnson syndrome/Toxic epidermal necrolysis (SJS/TEN), 2 cases of Drug reaction with eosinophilia and systemic symptoms (DRESS) and one case of acute generalised exanthematous pustulosis (AGEP) are causally related to the treatment, based on clinical and pathological features, and the compatible temporal relationship. Although the number of identified cases is limited, the reactions are serious and the association with vismodegib is plausible. The PRAC therefore recommends that the Product Information should be updated accordingly.

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 vismodegib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing vismodegib 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.