EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): sarilumab

Procedure No. EMEA/H/C/PSUSA/00010609/201907

Period covered by the PSUR: 13 January 2019 to 12 July 2019

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Scientific conclusions

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

A total of 213 cases reporting 220 events of pneumonia have been cumulative reported (95 cases from clinical trials and 118 from post-marketing). Of these, 85% were serious and 8 had a fatal outcome. From the 101 events (included in the 95 cases) from clinical trials, dechallenge (either permanent or temporarily) was reported in 64% of the events where this information was reported.

With regards to cellulitis, a total of 132 cases reporting 138 events of cellulitis have been cumulatively reported up to the DLP of this PSUR. Of these, 46% were from post-marketing. From the 80 adverse events of cellulitis reported in clinical trials, 33 were serious and 48 related (including 22 serious). From post-marketing, 57 of the 58 ADRs of cellulitis were serious.

The current SmPC for sarilumab states that "the most frequently observed serious infections with Kevzara included pneumonia and cellulitis" in both, section 4.4 under the warning of serious infections and in section 4.8 under the description of selected adverse reactions (infections).

In clinical trials, pneumonia and cellulitis were reported with a frequency of 2.8% and 2.9% respectively in the long-term safety population pool (Pool 2, as included in the Sarilumab's EPAR). In post-marketing, 118 cases of pneumonia and 61 cases of cellulitis have been reported.

However, pneumonia and cellulitis do not appear in the tabulated list of adverse reactions in Section 4.8 of the SmPC. Therefore, the PRAC requested pneumonia and cellulitis to be added to the tabulated list of adverse reactions in Section 4.8 with a frequency 'uncommon'. The Package leaflet is updated accordingly. In addition, there's a minor change in Section 4.8 to the tittle of the tabulated list of ADRs.

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