24 July 2014
EMA/602161/2014
Committee for Medicinal Products for Human Use (CHMP)

ILARIS

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: canakinumab

Procedure No. EMEA/H/C/001109/PSUV/0032

Period covered by the PSUR: 1 July 2013 – 31 December 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Ilaris, the scientific conclusions of PRAC are as follows:

1. Based on a review of the accumulated safety information for canakinumab, "Opportunistic infections" was identified by the MAH as a new safety finding and the MAH proposed to upgrade this risk from potential to an important identified risk in version 8.0 of the RMP submitted with this PSUR. In addition the MAH proposed to update section 4.4 to amend the current warning and specify which type of opportunistic infections, and to update section 4.8 of the SmPC to include that opportunistic infections have been reported in patients treated with canakinumab. Consequently section 4 of the Package Leaflet was proposed to also be amended.

2. Based on a review of accumulated safety information for canakinumab on "overdosage", the MAH proposed to update the RMP and section 4.9 of the SmPC to include that reported experience is limited and to include that higher doses than recommended have been administered in clinical trials without signs of acute toxicity.

3. Therefore, in view of available data, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Ilaris, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance canakinumab is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisations should be varied.