EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Soliris

International non-proprietary name: eculizumab

Procedure No. EMEA/H/C/000791/PSUV/0057

Period covered by the PSUR: 02.10.2012 – 01.04.2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

In view of available data regarding aspergillosis infections, the PRAC considered that changes to the product information were warranted. In total 16 cases of Aspergillus infections were identified in the MAH pharmacovigilance database. Fifteen (15) cases came from post-marketing reports while 1 was from a clinical trial. Of the 16 cases 12 had a fatal outcome, 1 associated with the use of Soliris in renal transplantation, 1 in heart transplantation, 5 in HSCT, 3 in the treatment of PNH, 1 each in the treatment of cold agglutinin disease and aHUS. In all the reported cases of Aspergillus infection, patients had significant underlying risk factors, including immunosuppression, exposure to construction or demolition, severe pancytopenia due to aplastic anaemia, and pre-existing lung impairment or Aspergillus infection prior to treatment with eculizumab. However, the role of eculizumab cannot be ruled out. Therefore the PRAC recommends the inclusion of Aspergillus infection into the list of adverse drug reactions in the Soliris Summary of Product Characteristics (SmPC) and in the package leaflet accordingly. Considering that one case was reported across the two trials (C10-001 and C10-002) (N=84), the incidence of Aspergillus infections is 1/84 or 1.2% (i.e. frequency ‘common’).

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 Soliris, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance ECULIZUMAB is favourable subject to the proposed changes to the product information.

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