21 July 2022
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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): osimertinib

Procedure No. EMEA/H/C/PSUSA/00010472/202111

Period covered by the PSUR: 13/11/2019 To: 12/11/2021

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Scientific conclusions

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

In view of available data on aplastic anaemia from clinical trials, the literature, spontaneous reports including in 4 cases a supportive temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between osimertinib and aplastic anaemia is at least a reasonable possibility. The PRAC concluded that the product information of products containing osimertinib should be amended accordingly.

In view of available data on left ventricular ejection fraction decreased from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, and a positive de-challenge, the PRAC considers a causal relationship between osimertinib and left ventricular ejection fraction decreased is at least a reasonable possibility. The PRAC concluded that the product information of products containing osimertinib should be amended accordingly.

In view of available data on cardiac failure from clinical trials, the literature, spontaneous reports including in some cases, a positive de-challenge or re-challenge, the PRAC considers a causal relationship between osimertinib and cardiac failure is at least a reasonable possibility. The PRAC concluded that the product information of products containing osimertinib should be amended 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 osimertinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing osimertinib 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.