CHMP recommends revoking the conditional marketing authorization for Adakveo® (crizanlizumab)

Basel, May 26, 2023 – The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended the revocation of the conditional marketing authorization (MA) for crizanlizumab, a once-a-month, humanized anti-P-selectin monoclonal antibody infusion indicated for the prevention of recurrent vaso-occlusive crises (pain crises) in sickle cell disease patients aged 16 years and older.

The CHMP recommendation has been provided to the European Commission (EC) and a final decision by the EC is expected within approximately two months.

The recommendation to revoke the conditional MA is based on a review of crizanlizumab under Art. 20 of Regulation (EC) No 726/2004[1], initiated by the EC following the results of the phase III study, STAND (NCT03814746), which did not demonstrate a statistically significant difference between crizanlizumab 5mg/kg or crizanlizumab 7.5mg/kg and placebo in annualized rates of vaso-occlusive crises leading to a healthcare visit over the first-year post randomization.

The STAND study findings are inconsistent with previous study results from SUSTAIN (NCT01895361), which demonstrated the superiority of crizanlizumab 5.0mg/ kg compared to placebo. Crizanlizumab's efficacy has also been demonstrated through open-label study data.

It is important to note that the STAND study results do not suggest new safety concerns with crizanlizumab. The overall safety profile of crizanlizumab remains consistent with the known profile of the commercially available 5.0mg/kg dose.

While we are disappointed by the recommendation to revoke the conditional MA for crizanlizumab in the European Union, we acknowledge that the STAND study did not meet one of the specific obligations of the conditional MA.

No new patients will be treated with crizanlizumab in the European Union. For patients currently on crizanlizumab, healthcare professionals should discuss alternative treatment options with them.

We continue to coordinate with health authorities globally.

We maintain our confidence in crizanlizumab as an important treatment option when used to reduce the frequency of sickle cell pain crises, based on the overall body of evidence available to date.

1. European Parliament, Council. Regulation No. 726/2004. Official Journal of the European Union. L 136/1. 2004.

1. https://dev.arctic.novartis.com/news/chmp-recommends-revoking-conditional-marketing-authorization-adakveo-crizanlizumab

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