European Commission (EC) adopts decision endorsing CHMP recommendation to revoke the conditional marketing authorization for Adakveo® (crizanlizumab)

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On 26 May 2023, the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended revoking the conditional marketing authorization (MA) for crizanlizumab.

On 3 August 2023, the European Commission endorsed the CHMP's recommendation, issuing a legally binding decision directly impacting all 27 European Union (EU) countries, as well as Iceland, Norway and Liechtenstein (as members of the European Economic Area), and Northern Ireland (which is following EU/EEA centralized procedures until January 2025).

In accordance with the European Commission's decision to revoke the conditional marketing authorization (MA) for crizanlizumab, Novartis will remove crizanlizumab from the EU/EEA market. Patients who are currently on treatment with crizanlizumab should speak with their healthcare professionals to discuss alternative treatment options.

The decision to revoke the conditional MA was based on a review of crizanlizumab under Article 20 of Regulation (EC) No 726/2004, initiated by the EC following the results of the phase III study, STAND (NCT03814746). The STAND study 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.

It's important to note that the STAND study results did not suggest new safety concerns with crizanlizumab.

Crizanlizumab remains approved for use by the United States Food and Drug Administration (FDA) for the reduction in frequency of vaso-occlusive crises (pain crises) in adults and pediatric patients aged 16 years or older with sickle cell disease. Novartis continues to discuss the STAND study results with the US FDA and other health authorities globally.
