26 January 2023
EMA/CHMP/37456/2023

CHMP List of questions

To be addressed by the marketing authorisation holder for Adakveo

Procedure under Article 20 of Regulation (EC) No 726/2004

Adakveo - EMEA/H/A-20/1525/C/4874/0013

Marketing authorisation holder(s): Novartis Europharm Limited

INN/active substance: Crizanlizumab

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

1. Questions

The marketing authorisation holder (MAH) is requested to address the following questions:

1. The MAH is asked to provide information on the estimated patient exposure to crizanlizumab in the different European Economic Area Member States and worldwide. This should include a line listing/details of and data from ongoing and completed clinical studies, non-interventional studies and post-marketing sources.
2. The MAH is asked to submit all available data from study A2301 (e.g. detailed safety and efficacy data, pre-planned analyses as per the latest study protocol). The MAH should also discuss the results in the context of all available data; this should include a discussion of any potential reasons for the discrepant interim results of study A2301 compared to the data available at the time of the conditional marketing authorisation.
3. The MAH is asked if any additional new data are available that were not submitted yet, e.g. from other (ongoing) clinical studies including from study A2202 or published literature. If so, a summary of these data should be provided.
4. Considering the above, the MAH should provide a full benefit-risk balance evaluation of crizanlizumab in the currently approved indication.
5. The MAH should provide a status and plan for study A2301 and discuss the impact on the fulfilment of the specific obligation (SOB).