



MEDICAL AND RESEARCH ADVISORY COMMITTEE (MARAC)

MARAC Statement About Crizanlizumab (Adakveo)

July 7, 2023 - SCDAAs Medical and Research Advisory Committee (MARAC) notes that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended on May 26, 2023, that the conditional marketing authorization for crizanlizumab (Adakveo) be revoked. The EMA stated that this revocation was triggered by the findings of the Novartis STAND multinational clinical trial showing no significant benefit of crizanlizumab over placebo in reducing pain or hospitalizations. Novartis reports that there were no safety problems in STAND. Abstract PB2512 submitted to the 2023 European Hematology Association reports no new safety issues in Novartis' post-marketing surveillance of over 5,000 patient-treatment-years.

Crizanlizumab was given United States Food and Drug Administration (FDA) approval in November 2019 and remains on the market in the U.S. Americans with sickle cell disease are still receiving this treatment. MARAC urges the FDA to keep crizanlizumab available for use in the U.S. while it awaits more detailed examination of the data so that individuals with sickle cell disease can benefit from this treatment.

The preliminary results from STAND were released by Novartis in a statement on January 27, 2023, but they have not been peer-reviewed nor published in detail. Preliminary results from other research studies on sickle cell disease with priapism or renal complications also await full peer-reviewed publication. MARAC urges Novartis to provide the full data from the STAND trial in peer-reviewed scientific presentation and publication.

LINKS:

Here is post-marketing surveillance abstract from EHA 2023: <https://library.ehaweb.org/eha/2023/eha2023-congress/387608/miguel.abboud.safety.of.crizanlizumab.in.patients.with.sickle.cell.disease.html?f=listing%3D0%2Abrowseby%3D8%2Aorderby%3D1%2Asearch%3Dpb2512>

For comparison, this is the statement from Novartis: <https://www.novartis.com/news/novartis-provides-update-phase-iii-stand-trial-assessing-crizanlizumab> accessed July 7, 2023

Statement from the UK SickleCellSociety: <https://www.sicklecellsociety.org/scs-response-to-european-medicines-agency-ema-and-committee-for-medicinal-products-for-human-use-chmp-updates-on-crizanlizumab/> accessed July 7, 2023

SPARTAN trial preliminary results in priapism abstract from ASH 2022: https://ashpublications.org/blood/article/140/Supplement%201/1636/489969/Interim-Analysis-of-a-Phase-2-Trial-to-Assess-the?utm_source=TrendMD&utm_medium=cpc&utm_campaign=Blood_TrendMD_0