Novartis provides update on Phase III STAND trial assessing crizanlizumab

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The preliminary results from the ongoing global phase III study STAND (NCT03814746) indicate no statistically significant difference between crizanlizumab 5mg/kg or crizanlizumab 7.5mg/kg and placebo in annualized rates of vaso-occlusive crises (pain crises) leading to a healthcare visit over the first-year post randomization. These findings are inconsistent with previous trial results from SUSTAIN (NCT01895361), which demonstrated the superiority of crizanlizumab 5.0mg/ kg compared to placebo.

It is important to note that the preliminary 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.

Since informing regulatory authorities, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has started a review of crizanlizumab to evaluate the impact of these results on its currently authorized use. Novartis is thoroughly reviewing the full data set of the STAND study. In order to determine the appropriate next steps, Novartis is working with regulators globally, including the EMA, which requested data from STAND as part of the conditions for marketing authorization, as well as with the United States Food and Drug Administration (FDA) and trial investigators.

Crizanlizumab was approved by the FDA in November 2019 for reduction in frequency of vaso-occlusive crises. In October 2020, the EMA granted conditional Marketing Authorization to prevent recurrent vaso-occlusive crises in patients aged 16 years and above, living with sickle cell disease.

While further assessment of the trial data is ongoing, physicians should consider the individual benefit and risks when making therapeutic decisions regarding the use of crizanlizumab.
