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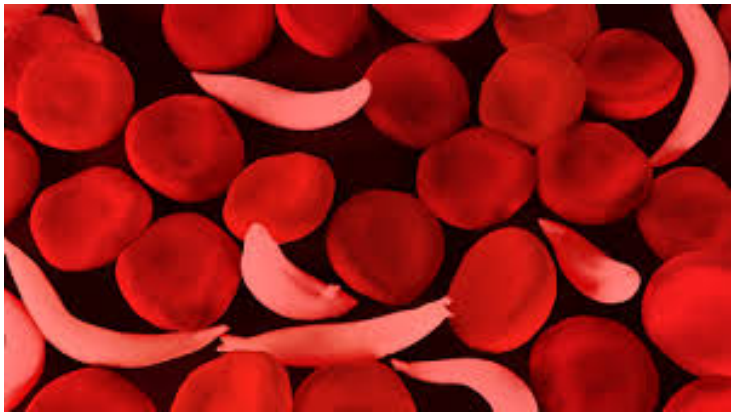
Novartis' sickle cell disease drug gets USFDA priority review status

17 July 2019 | News

FDA grants crizanlizumab Priority Review based on Phase II data showing prevention of vaso-occlusive crises (VOCs) in patients with sickle cell disease, shortening FDA review to six months from standard ten months



Novartis has announced the US Food and Drug Administration (FDA) accepted the company's Biologics License Application (BLA) and has granted Priority Review for its investigational sickle cell medicine crizanlizumab (SEG101). If FDA-approved, crizanlizumab is expected to represent the first monoclonal antibody targeting the P-selectin mediated multi-cellular adhesion in sickle cell disease.

Novartis submitted the application for crizanlizumab for the prevention of vaso-occlusive crises (VOCs) in patients with sickle cell disease (SCD) and was granted Breakthrough Therapy designation in December 2018. VOCs are unpredictable and extremely painful events that can lead to serious acute and chronic life-threatening complications and death. VOCs also lead to significant health care utilization. They are the most common cause of emergency room visits and hospital admissions for SCD patients, with total medical costs exceeding $1.1 billion annually in the United States.

Priority Review is granted to therapies that the FDA determines have the potential to provide significant improvements in the treatment, diagnosis, or prevention of serious conditions. The designation is intended to shorten the FDA review period to six months from the standard ten months.

"The FDA's decision to give crizanlizumab priority review reflects the impact that this medicine could have for the many thousands of US sickle cell adult patients who experience painful vaso-occlusive crises," said John Tsai, MD, Head of Global Drug Development and Chief Medical Officer, Novartis. "We are looking forward to the opportunity, if crizanlizumab is approved, to reimagine medicine in sickle cell disease for patients who live with this condition every day of their lives."