BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Novartis seeks FDA nod of brolucizumab for wet AMD patients

16 April 2019 | News

Novartis used a priority review voucher to expedite review of brolucizumab in the U.S. and, if approved by FDA, anticipates launching by the end of 2019



Novartis announced that the U.S. Food and Drug Administration (FDA) accepted the company's Biologics License Application (BLA) for brolucizumab (RTH258) for the treatment of wet age-related macular degeneration (AMD), also known as neovascular AMD, or nAMD.

Seeking to make brolucizumab available as quickly as possible, Novartis used a priority review voucher to expedite FDA review. If approved by the FDA, Novartis anticipates launching brolucizumab by the end of 2019.

Estimates suggest that by 2020, 1.5 to 1.75 million people in the U.S. will be living with wet AMD, a leading cause of blindness worldwide and a rapidly growing public health concern. As the disease progresses, patients may experience loss of central vision, resulting in an inability to complete daily tasks. Without treatment, vision can rapidly deteriorate and may lead to blindness.

The regulatory application is primarily based on Phase III data from the HAWK and HARRIER trials — prospective, randomized, double-masked multi-center studies.

"Wet AMD robs people of their precious sight and takes a major toll on the lives of millions of people who face not only vision loss, but also the burden of frequent injections into their eyes," said Dawn Prall George, executive director, The Support Sight Foundation. "We are always excited about potential new treatment options and hopeful they may help people manage this devastating disease."