Retinal vasculitis linked to Novartis' Beovu may limit uptake in wet AMD market

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Since the FDA approved the launch of Novartis' Beovu (brolucizumab) for the treatment of wet age-related macular degeneration (AMD) in the US in October 2019, the drug has been marketed in countries such as France, Germany, Italy, Spain, and the UK. Initially expected to eclipse the sales of standard-of-care therapies such as Roche / Genentech's Lucentis (ranibizumab) and Bayer's Eylea (aflibercept), Beovu is administered at 12-week intervals, compared to Lucentis and Eylea, which are injected every 6–8 weeks.

The low frequency of administration compared with options such as Lucentis and Eylea positioned Beovu as a drug with the potential to become a market-leading product in the wet AMD arena. However, hopes for Beovu to become a top-selling therapy may be dampened by the recent statement issued by the American Society of Retina Specialists (ASRS) that warned that a number of patients who were treated with the drug developed retinal vasculitis, which can lead to irreversible sight loss.

Intravitreal injections are typically administered in hospital settings and this may preclude patients who live in rural areas or have mobility issues from accessing treatment. The invasive route of administration is also linked to discomfort and this may negatively impact patient compliance rates. This urgent unmet need has been met with enthusiastic attempts by drug developers to manufacture therapies that are injected at trimonthly or quadrimestral intervals. Although the efficacy of anti-angiogenic therapies has long been documented in scientific literature, it is important that safety profiles are favourable as well, particularly as patients are often suffering from other conditions of ageing.

With a growing ageing population, the prevalence of AMD is set to increase over the next few years, meaning that more patients will require effective treatment options that are safe and reduce the impact of retinal vasculitis or sight loss on daily activities such as reading, driving, and recognizing people's faces.

In order to ensure that Beovu captures a large share of the lucrative wet AMD market, Novartis has initiated an internal and external review of the drug's safety. GlobalData expects that the findings of these proceedings will directly impact Beovu's uptake in some of the world's largest pharmaceutical markets.