Can approving brolucizumab for diabetic macular oedema redeem the drug's reputation in the market for retinal diseases?

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The entrance of Novartis' brolucizumab into the lucrative age-related macular degeneration (AMD) market was fraught with obstacles including immediate competition with popular drugs such as Bayer/Regeneron's Eylea (aflibercept) and Roche's Lucentis (ranibizumab) and Avastin (bevacizumab), the latter of which is available as an anti-neoplastic therapy that has efficacy in treating a range of different cancers. The most significant challenge brolucizumab has faced was the warning issued by the American Society of Retina Specialists that explained that a subset of patients who were treated with brolucizumab after its launch for AMD developed retinal vasculitis, a potentially sight-threatening inflammatory condition that affects blood vessels in the retina.

While AMD is one of the most prevalent retinal diseases that requires treatment with anti-angiogenic therapies, another condition that can benefit from treatment with these drugs is diabetic retinopathy. In particular, proliferative diabetic retinopathy and macular oedema are driven by new blood vessels growing in the retina, which causes damage to ocular structures and loss of central vision. Despite the risk of vasculitis and competition with other therapies with strong efficacy and safety profiles, brolucizumab may be better received by diabetic patients because of its expected low frequency of administration and the competitive annual cost of therapy (ACOT). Brolucizumab has the same ACOT as Eylea in the US, and because of the formulation of the drug, more of the monoclonal antibody can be concentrated in a given dose, making the therapeutic effect last longer. This significantly reduces the number of times a patient needs to come into the hospital or eye clinic to receive injections.

With approved therapies such as Eylea and Lucentis being recommended for monthly administration for optimal effects, brolucizumab has a chance of capturing a share of the diabetic retinopathy market by becoming a more convenient treatment option for patients. Furthermore, brolucizumab is in ongoing clinical trials to compare its safety and efficacy with that of Eylea in patients with diabetic macular oedema. If brolucizumab meets safety endpoints in these studies, the reputation of the drug could significantly improve and lead to impressive sales in a market that is characterised by non-compliance of patients due to the high proportion of diabetics who are in the labour force or are focusing on managing other comorbidities. Although brolucizumab holds promise in its ability to reduce the frequency of administration from every four weeks to 8–12-week intervals, the safety profile must be non-inferior to drugs used as the current standard of care, which are praised by ophthalmologists for being well tolerated by the vast majority of patients being treated.