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info@marketpublishers.com

Outlook of Diabetic Macular Edema – Current Landscape and the Way Forward

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Abstracts

Outlook of Diabetic Macular Edema – Current Landscape and the Way Forward: LONG-LASTING VEGF BLOCKERS, COMPOUNDS WITH VEGF- INDEPENDENT MECHANISM AND, TOPICAL AND ORAL TREATMENT OPTIONS, BRING THE QUEST FOR THE “IDEAL RETINAL DRUG” A STEP CLOSER

Global market for DME was ~$3.7 billion in 2019 with US alone contributing to 51% market share, owing to the higher incidence rates of diabetes amongst the developed nations. In 2018, ~2.4m people in the US had DME, of that only ~70% got diagnosed and treated. Following is the current treatment paradigm for DME - the first line includes Eylea (Regeneron), Lucentis (Roche/Genentech) and the second line treatment includes short term steroids implants such as dexamethasone (Ozurdex, Allergen; once every six months) or longer lasting fluocinolone acetonide (Iluvien, Alimera; once every three years). Anti-VEGFs lead the DME market due to its proven efficacy as compared to steroids, making it a premium priced segment. As a result of high cost, approved anti-VEGFs, the market witnesses extensive use of off-label us of Avastin (Roche/Genentech) and Triamcinolone acetonide - Kenalog (BMS). Despite being the last entrant in the anti-VEGF segment, Eylea has emerged as a leader owing to its superior efficacy with US market share ~69% by value ($4.6 billion) in 2019.

Although the multifactorial nature of DME has become clearer with involvement of several pathways, approved therapies target only one pathway and half of the patients continue to lose vision even after the treatments. In addition, high cost, adverse effects associated with intra-vitreal injections and limited patient convenience highlights the high unmet need. As a result, a few dozen initiatives are being undertaking to develop improved therapies for DME by a range of pharma companies globally. The late stage pipeline comprises of long-lasting VEGF blockers and compounds with VEGF-

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independent mechanisms such as Tie-2/Angiopoietin pathway modulators and integrin inhibitors. In the long run, non-invasive therapies (oral and topical), prophylactic treatment and gene therapy is likely to transform DME's treatment paradigm. Current major players in the DME market, including Regeneron and Roche, are focusing on maintaining the market share with formulations improvements reducing the frequency of administration, as their products heads for patent cliff. Despite biosimilars entry, the DME drug market in the US is estimated to grow rapidly (~ $2 billion - 2020) to reach $3.3 billion by 2025 (CAGR 10%), with over 90% contribution from anti-VEGF. In the coming decade, DME treatment is likely witness a paradigm shift from invasive injectable treatments to non-invasive options. The future therapies will empower ophthalmologists with better options to manage the debilitating condition without compromising the patient's vision and safety

This report provides insights into:

Epidemiology, multifactorial pathophysiology of DME, and significant role of inflammatory cascade in the progression of DME

Current treatment paradigm, clinical development outcomes of approved and off-label drugs, real-world data comparison of the approved therapies and limitations of the current therapies

Current and future market landscape of DME drugs (anti-VEGFs and steroids), along with the potential impact of biosimilars entry on the Innovator molecules

In depth analyses of development pipeline (Pre-clinical -PhIII), while identifying the novel therapies with the potential to change the treatment paradigm

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