Diabetic Macular Edema | Decision Base | US | 2015

Diabetic macular edema (DME) is a vision-threatening condition affecting nearly 5 million people in the seven major markets under study (United States, France, Germany, Italy, Spain, United Kingdom, and Japan), and the prevalent population is anticipated to grow to million by 2023. The anti-vascular endothelial growth factor (VEGF) agent ranibizumab (Roche/Genentech/Novartis's Lucentis) was approved for the treatment of DME in 2012, and three pharmacotherapies with unique mechanisms of action and delivery profiles were approved in 2014, resulting in several treatment options. However, even with these new choices available, surveyed retinal specialists and managed care organization pharmacy directors (MCO PDs) indicate that opportunity remains for therapies that offer more-novel delivery profiles, reduced dosing frequency, and the ability to improve visual acuity to a greater extent than can be achieved with current agents.

Questions Answered in This Report:

- Improvement in visual acuity and improvement on optical coherence tomography (OCT) central retinal thickness are key goals in the treatment of DME. What are the key primary and secondary clinical trial end points with which new therapies are evaluated? How do U.S. and European retinal specialists weight specific efficacy end points and other drug attributes in their prescribing decisions for DME?

- Less-frequent dosing and improvement in and maintenance of visual acuity are key areas of unmet need in DME, according to surveyed U.S. and European retinal specialists. Which therapies in development for DME are poised to fulfill these needs? What clinical and/or regulatory challenges must drug developers overcome in order to capitalize on these areas of unmet need? What degree of improvement over currently available therapies do surveyed U.S. MCO PDs seek from new therapies on key clinical attributes for which surveyed physicians indicate there is high unmet need? In order to meet these current needs, are retinal specialists and MCO PDs willing to accept a role for adjunctive therapy in the treatment algorithm?

- The percentage of patients with vision improved at 24 months, mean change in visual acuity at 24 months, dosing frequency, and dosing formulation are key drivers of physicians' prescribing decisions and are the focus of drug development for new DME therapies. What trade-offs across these and other clinical attributes are U.S. retinal specialists willing to make when considering the use of emerging therapies for the treatment of DME? Based on the trade-offs in price and performance across key drug attributes that U.S. retinal specialists are willing to make, how do physician preference and prescribing likelihood vary across different target
Despite the potential launch of several emerging therapies in the DME market over the next ten years, aflibercept (Regeneron/Bayer HealthCare/Santen’s Eylea) will remain the gold-standard therapy in our Drug Comparator Model. On what clinical attributes is aflibercept most differentiated from its competitors? What are the weaknesses of this therapy on which emerging therapies can capitalize? Which emerging therapies, if any, pose the greatest threat to aflibercept as well as the other key current therapies?

Scope:
Attributes included in conjoint analysis-based assessment of target product profiles for DME:
- Percentage of patients with vision improved at 24 months.
- Mean change in visual acuity at 24 months.
- Incidence of serious ocular side effects.
- Incidence of serious nonocular side effects.
- Dosing frequency.
- Dosage formulation.
- Price per year.

Attributes included in assessment of U.S. payers’ receptivity to new therapies for DME:
- Efficacy: improvement in visual acuity.
- Delivery: improved frequency of maintenance dosing.
- Delivery: novel delivery profiles.
- Efficacy: improvement in visual acuity as an adjunctive therapy.

Physicians surveyed: 60 U.S. and 31 European retinal specialists.
Payers surveyed: 22 U.S. MCO PDs.

Comprehensive List of Therapies Included in Our Research and Modeling:

Current Therapies
- Ranibizumab (Roche/Genentech/Novartis’s Lucentis)
- Aflibercept (Regeneron/Bayer HealthCare/Santen’s Eylea)
- Bevacizumab (Roche/Genentech/Chugai’s Avastin)
- Fluocinolone acetonide (Alimera Sciences’ Iluvien)
- Dexamethasone (Allergan’s Ozurdex)

Emerging Therapies
- Abicipar pegol (Allergan/Molecular Partners)
- Low-dose danazol (Ampio Pharmaceuticals’ Optina)
- Squalamine (Ohr Pharmaceutical)
- PF-04634817 (Pfizer)
- AKB-9778 (Aerpio Therapeutics)

Report Details
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