Multiple Sclerosis (Relapsing-Remitting) | Decision Base | US | 2015

The relapsing-remitting multiple sclerosis (RR-MS) therapy market continues to be developmentally active and commercially compelling, even with the steady increase in the number of approved disease-modifying therapies (DMTs) in recent years. Drug-treatment rates for RR-MS are high, despite a small diagnosed prevalent population relative to many other neurological indications, and neurologists emphasize early treatment intervention to improve long-term outcomes in this chronic disease. Given that the MS disease course is heterogeneous and unpredictable, substantial opportunity remains for more-effective, safer, more-tolerable, and less-burdensome treatment alternatives.

Questions Answered in This Report:

- A drug’s performance on at least eight efficacy end points, including reduction in annualized relapse rate (ARR) over two years versus placebo, is important for drug approval and physician use. What are the key primary and secondary clinical trial end points with which new therapies are evaluated? How do U.S. and European neurologists weight efficacy measures and other drug attributes in their prescribing decisions for RR-MS?

- Glatiramer acetate (Teva’s Copaxone) is the 2013 major-market sales leader for RR-MS. What weaknesses exist in its profile that would allow emerging therapies to gain a foothold in the market? Have emerging therapies demonstrated strength on the attributes that surveyed neurologists indicate are the most important in their prescribing decisions? Which emerging therapies will offer the clinical improvements over currently available therapies that surveyed managed care organization pharmacy directors (MCO PDs) seek from new therapies?

- Reduction in ARR versus placebo and price per day are key drivers of physicians’ prescribing decisions and/or are the focus of drug development for new RR-MS therapies. What trade-offs across these and other clinical attributes are U.S. neurologists willing to make when considering the use of emerging therapies for the treatment of RR-MS? Based on the trade-offs in price and performance across key drug attributes that U.S. neurologists are willing to make, how do physician preference and prescribing likelihood vary across different target product profiles for RR-MS?

- By 2018, alemtuzumab (Sanofi/Genzyme/Bayer HealthCare’s Lemtrada) will emerge as the gold-standard therapy in our Drug Comparator Model because of its superior clinical profile over the key current therapies we evaluated. On what clinical attributes is alemtuzumab most...
differentiated from its competitors? Which current therapies are at greatest risk of being replaced by alemtuzumab?

**Scope:**

Attributes included in conjoint analysis-based assessment of target product profiles for RR-MS:

- Reduction in ARR versus placebo.
- Reduction in risk of three-month sustained disability progression (SDP; i.e., Expanded Disability Status Scale [EDSS] progression) versus placebo.
- Rate of serious side effects (e.g., opportunistic infections, autoimmune adverse events).
- Rate of nonserious side effects (e.g., injection-site reactions, flu-like symptoms).
- Delivery profile (i.e., dosing frequency and formulation).
- Monitoring: frequency (e.g., monthly) and complexity (e.g., number/difficulty of tests).
- Price per day.

Attributes included in assessment of U.S. payers’ receptivity to new therapies for RR-MS:

- Efficacy: improved effect on ARR versus interferon-beta (IFN-β) at two years.
- Efficacy: improved effect on freedom from disease activity versus IFN-β at two years.
- Efficacy: improved effect on brain atrophy versus IFN-β at two years.
- Safety: improved monitoring profile.

Physicians surveyed: 61 U.S. and 30 European neurologists.

Payers surveyed: 20 U.S. MCO PDs.

**Comprehensive List of Therapies Included in Our Research and Modeling:**

**Current Therapies**

- Glatiramer acetate (Teva’s Copaxone)
- IFN-β-1a intramuscular (Biogen Idec’s Avonex)
- Natalizumab (Biogen Idec’s Tysabri)
- Fingolimod (Novartis/Mitsubishi Tanabe Pharma’s Gilenya/Imusera)
- Dimethyl fumarate (Biogen Idec’s Tecfidera)

**Emerging Therapies**

- Alemtuzumab (Sanofi/Genzyme/Bayer HealthCare’s Lemtrada)
- Daclizumab (AbbVie/Biogen Idec’s Zinbryta)
- Ocrelizumab (Roche/Genentech)
- Laquinimod (Teva/Active Biotech’s Nerventra)
- RPC-1063 (Receptos)

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