Multiple Sclerosis (Chronic-Progressive) | Decision Base | US | 2014

Despite contributing a relatively modest fraction to the overall multiple sclerosis (MS) population, the chronic progressive MS (CP-MS) subpopulation (comprising secondary-progressive MS [SP-MS] and primary-progressive MS [PP-MS]) presents considerable opportunity for the development of novel therapeutics. PP-MS patients, in particular, are significantly underserved at present due to the complete lack of proven effective disease-modifying therapies as a result of the repeated failure of clinical trials in this patient subtype to date. However, a growing number of current and emerging therapies are being evaluated specifically in the PP-MS subpopulation. Surveyed neurologists and managed care organization pharmacy directors (MCO PDs) both identify a greater effect on physical disability as one of the top unmet needs in PP-MS. Indeed, in terms of impact on prescribing decisions, improvements in efficacy will likely outweigh comparable improvements in other areas such as safety and delivery.

Questions Answered in This Report:

• Delaying the progression of physical disability is a key goal in the treatment of PP-MS. 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 specific efficacy end points and other drug attributes in their prescribing decisions for PP-MS?

• Therapies with a greater effect on physical disability or a greater effect on quality of life are key areas of unmet need for PP-MS according to the insights of surveyed U.S. and European neurologists. Which therapies in development for PP-MS are poised to fulfill these needs? What clinical and/or regulatory challenges must drug developers overcome 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?

• A therapy’s reduction in disability progression (as measured by the Expanded Disability Status Scale [EDSS]) and its incidence of serious or life-threatening side effects are key drivers of physicians’ prescribing decisions and/or are the focus of drug development for new PP-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 PP-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 PP-MS?
Based on its clinical profile, glatiramer acetate (Teva’s Copaxone) is the current clinical gold standard in our Drug Comparator Model. What attributes do thought leaders believe differentiate this therapy from competing current therapies and emerging therapies? Will any therapies in development challenge glatiramer acetate as the future gold standard in 2017 or 2022?

**Scope:**

Attributes included in conjoint analysis based assessment of target product profiles for PP-MS:
- Reduction in EDSS progression relative to placebo.
- Reduction in brain atrophy relative to placebo.
- Incidence of serious or life-threatening side effects (e.g., opportunistic infections, autoimmune adverse events, malignancy, cardiac risk).
- Incidence of less serious side effects (e.g., injection site reactions, flu-like symptoms, flushing, GI side effects).
- Monitoring burden: frequency (e.g., first-dose only, monthly) and complexity (e.g., number/difficulty of unique tests, need for referrals).
- Delivery burden (i.e., dosing frequency and formulation).
- Price/day.

Attributes included in assessment of U.S. payers’ receptivity to new therapies for PP-MS:
- Effect on EDSS progression.
- Effect on MRI brain volumetric measures.
- Rate of serious adverse events (e.g., serious infections, including opportunistic infections such as progressive multifocal leukoencephalopathy [PML], malignancy, cardiac risk).
- Monitoring burden, taking into account both the frequency and complexity of monitoring required.

Physicians surveyed: 60 U.S. and 31 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)
- Interferon-β-1a (IM) (Biogen Idec’s Avonex)
- Interferon-β-1b (Bayer HealthCare’s Betaseron/Betaferon, Novartis’s Extavia)
- Interferon-β-1a (SC) (Merck Serono/EMD Serono/Pfizer’s Rebif)
- Natalizumab (Biogen Idec’s Tysabri)
Emerging Therapies

- Fingolimod (Novartis/Mitsubishi Tanabe Pharma’s Gilenya/Imusera)
- Ocrelizumab (Roche/Genentech)
- Daclizumab (AbbVie/Biogen Idec)
- Laquinimod (Teva/Active Biotech’s Nerventra)
- Alemtuzumab (Genzyme/Sanofi/Bayer HealthCare’s Lemtrada; approved in Europe in 2013)

Report Details

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