

Multiple Sclerosis: KOL Insight

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Abstracts

Roche's/Biogen's novel ocrelizumab is set to radically alter the Multiple Sclerosis (MS) treatment paradigm. Which companies and products will lose market share as its use widens and what clinical benefits underpin KOL excitement? Could it challenge interferon therapy? Where will oral therapies such as Novartis' Gilenya (fingolimond) fit in? Where will Biogen's well regarded Tecfidera (dimethyl fumarate) find a role?

This report reveals the unique insights of 12 leading US and European KOLs – see who they are. How they view the clinical benefits of current and late-stage disease-modifying agents, safety concerns and the influence patients exert are fully explored. The report analyses 8 leading launched products and 8 significant late-stage therapies see full list.

View: US KOLS, EU KOLS, Market drugs, Pipeline drugs

“Ocrelizumab is the most exciting of all the MS drugs. This drug will take markets. This will be the most disruptive therapy of any therapy we've discussed.” EU KOLv

Answering key questions

Ocrelizumab: What safety and dosage benefits underpin KOLs positive opinions about ocrelizumab?

Copaxone/Glatopa: Will longer acting formulations help Teva defend Copaxone revenues against Sandoz/Momenta's Glatopa (generic glatiramer acetate)?

Gilenya/Tecfidera: Have safety concerns blunted the growth of Novartis'Gilenya (fingolimond) and Biogen's Tecfidera (dimethyl fumarate) - how do KOLs see their role in the treatment paradigm evolving?

Plegridy: How is the launch of Plegridy impacting other interferon products and what effect will this have on the interferon market as a whole?

Lemtrada: How might the CAM-THY, EMERALD and TOPAZ trials for Sanofi's/Genzyme's Lemtrada (alemtuzumab) influence KOLs views?

Ozanimod/siponimod: Can new sphingosine modulators such as Celgene's ozanimod, Novartis' siponimod and Actelion's ponesimod differentiate themselves against established therapies and find a market?

Biotin: MedDay's ultra-high dose biotin (MD 1003) is showing promise for progressive disease and could be an effective low-cost treatment – but what KOL concerns do MedDay have to address in clinical trials?

Top Takeaways

A changing treatment paradigm: While ocrelizumab will initially compete as a second line in RRMS it could move to first line therapy and get traction in PPMS. Understand its clinical benefits and why it is being seen as a really potent alternative to current products.

A question of safety: Many treatments are effective in treating MS but come with a range of adverse reactions. Assess the impact safety is having on prescribing habits and how new therapies will benefit.

Patient preferences: Appreciate how patient choice plays a key role in prescribing decisions. The route of administration and frequency of treatment are critical to patient buy-in and healthcare cost control.

The next generation: Understand why Anti-LINGO could be the next game changer in multiple sclerosis.

Underserved patient populations: While there are plenty of options for the treatment of RRMS, there remains an unmet need for progressive forms of the disease – how will new treatments play a role?

Combination Therapy: Most MS treatments are given as monotherapy, and cost is cited as the dampener of combination treatment. Could innovative pricing be

an opportunity area and would the clinical benefits justify the increase?

Research points the way: Review KOL attitudes to recently completed or ongoing clinical trials such as BEST-MS, CAM-THY, ORATORIO, OPTIMUM, ARPEGGIO and EXPAND.

Key Issues Explored

Patients play a critical role in therapy choice. The frequency of treatment, additional monitoring and fear of adverse reactions are just some of the issues that clinicians take into account. It's more than just efficacy and there are lessons for companies for their patient outreach programmes.

There is much promise in the new therapies coming to market but they are competing with established products whose profile and risks are known – it will take some time to build clinical confidence and start to fully realise their potential - medical and patient education will play a key role.

Product differentiation is critical in getting formulary placement. Knowing what product attributes and patient characteristics KOLs think are the most important in terms of prescribing decisions are “must-know” to ensure commercial success.

Unlike many treatment areas, combination therapy is not common in MS. KOLs cite cost as an issue, but could progressive pricing and combination therapy be considered as an end game for products superseded by new therapies?

How do KOLs view high-dose biotin (MD 1003) and what specific advantages would such a product have?

A report based on expert knowledge

US KOLs

Dr Robert Naismith, MD, Associate Professor of Neurology and Neurology Clerkship Director at Washington University in St. Louis

Dr Benjamin M. Greenberg, MD, Associate Professor and the Cain Denius Scholar in Mobility Disorders in the Department of Neurology and Neurotherapeutics at UT Southwestern Medical Center

Dr Daniel Harrison, MD, Assistant Professor of Neurology at Johns Hopkins University Medical Center and a faculty member of the Johns Hopkins MS Center

Dr Shiv Saidha, M.B.B.Ch, Assistant Professor of Neurology at Johns Hopkins University School of Medicine

Dr Darin T. Okuda, MD, Director of the Multiple Sclerosis and Neuroimmunology Imaging Program and the Deputy Director of the MS Program and Clinical Center for Multiple Sclerosis at the University of Texas Southwestern Medical Center in Dallas, Texas

Dr Anne Cross, MD, Professor of Neurology and Section Head of Neuroimmunology at Washington University School of Medicine, St. Louis

EU KOLs

Prof Cris Constantinescu, Head of the Academic Division of Clinical Neurology at the University of Nottingham; senior consultant in charge of the MS Clinic, University Hospital Nottingham

Prof Nighoghossian, Chief Neurologist at CHU Lyon, France

clinic in a university hospital.

Dr Elio Scarpini, Chief of the Center for Neurodegenerative and Demyelinating Disorders, University of Milan, Fondazione IRCCS Cà Granda, Ospedale Policlinico, Milan, Italy

Dr Belen Caminero, is responsible for the Multiple Sclerosis Unit in the Healthcare Complex of Avila, Spain.

Anonymous, German KOL, is a Professor of Neurology. This expert is Managing Lead Consultant of a neurology

Anonymous, European KOL, Principal investigator on several multinational MS clinical trials

Get KOL insights on

Marketed MS Drugs

Interferons (Avonex, Rebif, Betaseron, Extavia)

Plegridy (peginterferon beta-1a/BIB017; Biogen)

Copaxone (glatiramer acetate; Teva)

Tecfidera (dimethyl fumarate; Biogen)

Aubagio (teriflunomide; Sanofi/Genzyme)

Gilenya (fingolimod; Novartis/Mitsubishi Tanabe Pharma)

Tysabri (natalizumab; Biogen)

Lemtrada (alemtuzumab; Sanofi/Genzyme/Bayer HealthCare)

MS Pipeline

Zinbryta (daclizumab high-yield process, DAC-HYP; Biogen/AbbVie)

Nerventra (laquinimod; Active Biotech/Teva)

Ozanimod (RPC 1063; Celgene)

Siponimod (BAF 312; Novartis)

Ponesimod (ACT 128800; Actelion)

Ocrelizumab (Roche/Biogen)

Masitinib (AB 1010; AB Science)

Biotin (MD 1003; MedDay)

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