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Multiple Sclerosis [2016]: Bulletin #3

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Abstracts

This edition presents the views and insights from three key opinion leaders (KOLs) from the US and Europe on a variety of recent events in the multiple sclerosis (MS) treatment landscape. Topics covered include; Roche reporting that a German patient with MS has developed progressive multifocal leukoencephalopathy (PML) following three years of treatment with Tysabri (natalizumab; Biogen) and one dose of Ocrevus (ocrelizumab); Merck Group announcing that the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for approval of Mavenclad (cladribine) for the treatment of relapsing forms of multiple sclerosis (RMS) in patients with high disease activity, and presenting new data on cladribine's mechanism of action; and The European Medicines Agency's (EMA) provisionally restricting the use of Zinbryta (daclizumab; Biogen/AbbVie) due to a patient's death from liver injury (fulminant liver failure), to patients with highly active relapsing disease that has failed to respond to certain other treatments, and to patients with rapidly evolving relapsing disease who cannot be treated with other medicines.

Business Questions:

Do KOLs believe that Ocrevus was the cause of this case of PML, or are other factors at play?

What impact will the news of this case of PML have on the prescribing of Ocrevus in the US, and will the news cause any change to patient monitoring requirements?

Was the FDA right to include a warning of the risk of PML on Ocrevus' label, despite no cases of PML being seen in the pre-approval setting?

What has been the reaction to the recommendation for approval of cladribine in

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Europe, and will Merck Group’s new data for cladribine dispel concerns about increased risk of malignancy?

How concerned are KOLs about patient segmentation and eligibility for cladribine?

Will Merck Group be able to leverage cladribine’s mechanism of action when it comes to differentiating it compared to other treatments?

Assuming full approval, where do KOLs see cladribine being used in the MS treatment paradigm, and which products are likely to lose market share?

Do KOLs believe that the EMA’s decision to restrict the use of Zinbryta in Europe was justified?

What impact will the EMA’s restriction have on the prescribing of Zinbryta in the US and Europe, and will the restriction be lifted any time soon?

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