<26th Annual Meeting of the European Charcot Foundation>

<Baveno, Italy 15–17 November 2018>

Abstract submission deadline: 14th September 2018

Presentation preference: Oral or Poster

Current word count: 291/300

Short title (max. 45 characters): Interferon β-1a: 10 years of the UK RSS

Title: Subcutaneous Interferon beta-1a, 10-Year Results from the United Kingdom Multiple Sclerosis Risk Sharing Scheme

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Introduction: It is estimated that the cumulative exposure to subcutaneous interferon beta-1a (scINF-β1a; Rebif®) since its introduction to the European market in 1998 amounts to approximately 1,616,700 patient-years in the post-marketing setting. The UK Department of Health (DoH) established the MS Risk Sharing Scheme (RSS), to provide patients with relapsing-remitting multiple sclerosis (RRMS) access to disease-modifying treatments (DMTs), with price adjustment provisions to maintain cost-effectiveness.

Objectives: Our aim is to present the final year 10 RSS results for patients treated with scINF-β1a.

Methods: NHS patients meeting eligibility criteria and treated with DMTs entered the RSS. Disease progression was assessed by Expanded Disability Status Scale (EDSS) at 2 year intervals. Disease course was modelled based on baseline EDSS and long-term natural history (NH) data (British Columbia). 'Target' hazard ratios (HRs) applied to the NH data allowed comparison of actual vs. target health related quality of life (utility) weighted EDSS. A shortfall in treatment benefit that exceeded 10% would trigger price adjustments to restore cost-effectiveness. HRs which would produce zero shortfall were deemed the 'implied HRs' (HRs <1 indicate treatment benefit).

Results: The Year 10 primary analysis involved 1635 scIFN-β1a-treated patients (mean baseline EDSS: 2.92; observed mean Year 10 EDSS: 4.12). Baseline, Year 10 expected untreated, and Year 10 expected with treatment, utility-weighted EDSS was 0.618, 0.486, and 0.535 respectively (actual observed utility-weighted EDSS: 0.534). Thus, RSS outcomes were in-line with expectation. The actual 2.6% shortfall reduced to zero with an implied HR of 0.77.

Conclusion: The UK DoH criteria for cost-effective provision of scINF-β1a were fulfilled throughout the 10 years of the RSS. The final RSS 10 year analysis provides long-term evidence, within the context of a large scale 'real-world' evaluation, of the treatment benefit provided to patients with RRMS by scINF-β1a.

Disclosures: Funded by Merck KGaA, Darmstadt, Germany

Author Disclosures

GH is an employee of Merck Serono Ltd., a division of Merck KGaA, Darmstadt, Germany

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