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LONDON, UK (GlobalData), 22 October 2012 - The **28th Congress** of the **European Committee for Treatment and Research in Multiple Sclerosis** (ECTRIMS) played host to promising data that aim to address one of the greatest unmet needs in Multiple Sclerosis (MS): the **treatment** for progressive forms of the disease. Although **Primary-Progressive MS** (PPMS) afflicts only 10%–15% of the MS population, a significant proportion of patients with **Relapsing-Remitting** MS (RRMS) eventually advance to a **Secondary-Progressive disease stage** (SPMS). Despite the surge in drug R&D in recent years, effective treatments directed at the progressive MS phase are still lacking, with most current **Disease-Modifying Therapies** (DMTs) providing limited or no clinical efficacy. Hence, there remains an opportunity for pharmaceutical companies to target this underserved subset of MS patients.

Among the hotly anticipated data presented at ECTRIMS 2012 were the results from a Phase II non-commercial clinical trial evaluating the effectiveness of statins for SPMS. In the

randomized, double-blind MS-STAT study involving 140 SPMS patients, daily simvastatin treatment (80mg) had a statistically significant benefit over placebo in reducing brain atrophy and delaying disease progression. The potential impact of statins on the treatment regimen of MS is sizeable. Having already established itself in the cardiovascular space, the good safety and tolerability profile of statins is well known, and could potentially be used in combination with current DMTs. In addition, statins exert no immunomodulatory effects, so treated patients are not at risk of opportunistic infections due to a compromised immune system, a major advantage over most current MS DMTs. While a Phase III trial using simvastatin is warranted, securing the necessary funding of upwards of $500m could represent a challenge, as pharmaceutical companies may be reluctant to invest in a drug whose patent expired in 2006.

Biogen Idec's and Elan's Tysabri (natalizumab) also generated much interest, after a Phase IIa proof-of-concept study demonstrated the efficacy of Tysabri in reducing inflammation, axonal damage and demyelination in 17 progressive MS patients. Since gaining FDA approval in 2004, Tysabri has struggled to establish itself in the MS treatment algorithm, owing to safety concerns and the increasingly competitive RRMS therapy landscape. With the distinct lack of approved treatments for progressive MS, the positive data presents Tysabri with an opportunity to increase its share in the lucrative $9.8 billion MS market. The data provides promising developments towards future therapeutic options for patients with a PPMS or SPMS phenotype.

In additional highlights from ECTRIMS 2012, efficacy data from Novartis, Sanofi/Genzyme and Biogen Idec have stoked the fire in the race to dominate the oral MS drug market. Following its approval in 2010, Novartis's Gilenya tackled a key unmet need in MS in becoming the first oral DMT to reach the market for RRMS, and allowing patients intolerant to injected drugs to benefit from treatment. The subsequent FDA approval of Sanofi's Aubagio (teriflunomide) last month and the anticipated arrival of Biogen Idec's BG-12 (dimethyl fumarate) have created increased competition and rivalry between the three pharmaceutical powerhouses.

In the studies presented, treatment with BG-12 (240mg), Gilenya (0.5mg) and Aubagio (7mg and 14mg) all elicited a significant dose-dependent reduction in Annualized Relapse Rate (ARR) in RRMS patients, by 49%, 48% and 22.3%–36.3% respectively when compared to placebo-treated patients, with additional benefits in delaying disability progression. Consistent with previous trials, BG-12 combines strong efficacy with a favorable safety profile. This gives it an important advantage over Gilenya and Aubagio, both of which are associated with a risk of serious adverse reactions. Despite its apparently lesser efficacy, however, physicians and patients might prefer Aubagio as it is currently priced at $45,000 per year, which is less than Gilenya ($57,600) and BG-12 (predicted to cost $50,000).

Overall, the findings from ECTRIMS 2012 have brought a lot of excitement to the MS community, with substantial progress made in attempting to tackle a debilitating disease affecting more than 2.5 million people worldwide.