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Efficacy and safety of fingolimod treatment in multiple sclerosis: The clinical experience of the AUBMC Multiple Sclerosis Center in Lebanon

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Background: Fingolimod is the first oral disease- modifying therapy (DMT) approved by the US Food and Drug Administration (FDA) in September 2010 and by the European Medicines Agency (EMA) in March 2011 for the treatment of relapsing-remitting multiple sclerosis (RRMS). The available efficacy and safety data of fingolimod derives from the two completed Phase III clinical trials, FREEDOMS and TRANSFORMS which demonstrated a reduction in the relapse-rate, disability progression and gadolinium- enhancing lesions compared to placebo and intramuscular interferon beta 1a. However, there are still no or few data about the real-world efficacy and safety of fingolimod, at least after one year of treatment in the Middle East region. Objective: To describe our clinical experience with fingolimod looking at different outcomes including efficacy, tolerability and safety in multiple sclerosis (MS) patients presenting to our MS Center.

Methods: MS patients who were treated with fingolimod and visited our AUBMC-MS Center from October 2011 to December 2013 were identified. Demographics, MS disease related variables, first-dose and follow up recorded adverse events and efficacy outcomes were extracted from our medical charts. Main efficacy outcomes were the annualized relapse rate (ARR), the disability progression (EDSS) and the magnetic resonance imaging (MRI) activity.

Results: Eighty seven RRMS patients who were prescribed fingolimod were included in the analysis. Fifty eight were women and 29 men. Mean disease duration was 6.876.1 years and mean EDSS at fingolimod initiation was 2.3371.4. Eight patients received fingolimod between 3 and 5 months, 26 patients received treatment between 6 and 11 months, 32 patients between 12 and 23 months, and 21 patients 424 months. First dose observation was uneventful in all patients. Within a period of 14.978 months, treatment was discontinued in 21 patients (24.4%) due to progression of the disease to secondary progressive MS (n=6), lack of efficacy (n=10), pregnancy (n=1), recurrent infections (n=1), varicella zoster virus (VZV) radiculitis (n=1), and patients' personal decision (n=2). ARR in the year previous to fingolimod treatment was 1.31 and decreased to 0.26 during the overall treatment period. In patients treated with fingolimod for o12 months (n=53), 60.4% were free from EDSS progression and 62.3% were free from MRI activity.

Conclusion: In our study patients, fingolimod was safe, well tolerated and effective in reducing disease activity and progression of disability.