Patient Reported Outcomes, Safety and Tolerability in the Open Label Period of GA Depot, Phase 3, Multinational, Double-Blind, Placebo-Controlled Study in Patients with Relapsing Forms of Multiple Sclerosis

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BACKGROUND

Glatiramer Acetate Depot (GA Depot) is a novel long-acting GA formulation consisting of extended-release microspheres containing GA, administered IM every 28 days. GA Depot significantly reduced the annualized relapse rate and the number of new enhanced lesions in the double-blind, randomized, placebo controlled (PC) phase 3 study in relapsing forms of Multiple Sclerosis (RMS).

OBJECTIVE

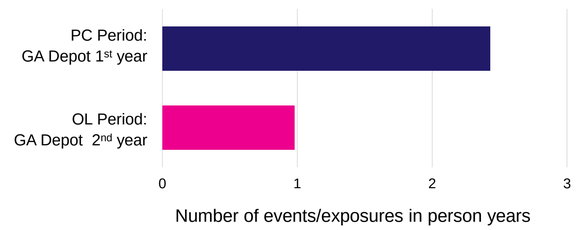
To assess GA Depot safety, tolerability, Quality of Life and treatment satisfaction in patients with RMS in the open label (OL) period of the study.

DESIGN/METHODS

Patient Reported Outcomes (PROs) were assessed using two validated questionnaires: the EQ-5D-3L & the TSQM-9 at visit 16 (week 52, baseline for OL period) & visit 29 (week 104, end of OL period). In the OL period, 763 patients: 347 treated with GA Depot in the PC period (cGA Depot group) & 416 that received placebo during the PC period (pGA Depot group), received at least one dose of GA Depot. PRO population included all OL completers (625 patients (81.9%)) for all descriptive analyses and patients with both visits 16 & 29 for longitudinal analysis. Safety and tolerability outcomes included adverse events (AEs) & serious adverse events (SAEs) & injection site reactions (ISRs) analyzed by yearly event rate or incidence and compared to the 1st year of treatment (PC period).

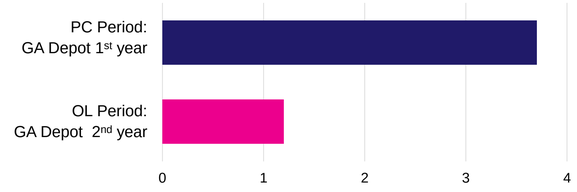
RESULTS

Figure 1: ISR rate



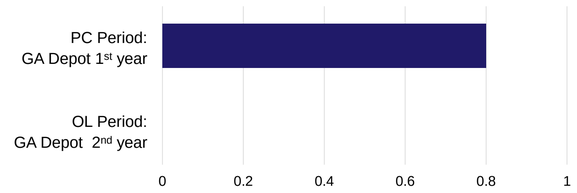
ISRs rate in the cGA Depot group was significantly lower in the OL period (0.98) compared to the PC period (2.43).

Figure 2: SAEs %



SAE incidence was lower in the cGA Depot group 4 (1.2%) patients in the OL period vs. 19 (3.7%) patients, after excluding Covid-19 cases, in the PC period.

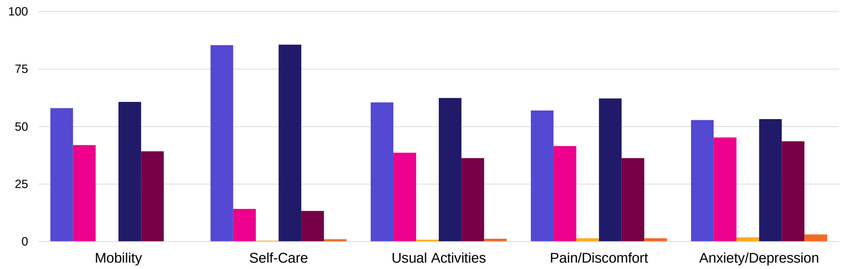
Figure 3: IPIRs %



No Immediate Post-Injection Reactions (IPIRs) (as defined in the glatiramer acetate FDA label) were detected in the OL period vs. 0.8% in the PC period.

Figure 4: EQ-5D-3L V16 & V29

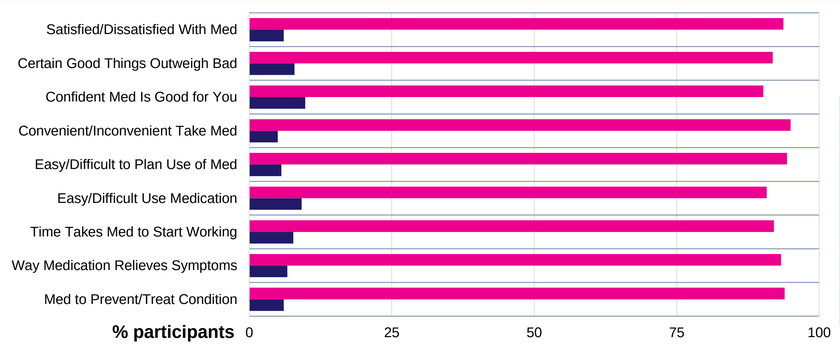
At visit 29, the majority of the patients reported no problems in all dimensions of the EQ-5D-3L: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.



	Visit 16	Visit 29
No problems		
Some problems		
Extreme problems		

A significant improvement was assessed by the percent change in EQ-5D-3L VAS from visit 16 (mean percent change 8.34, p = 0.0162). The percentage of patients that maintained or improved at visit 29 was significantly higher than that of patients worsening (p<0.001).

Figure 5: TSQM-9 Questionnaire Descriptive statistics by Question (grouped answer) V29



The TSQM-9 showed that >90% of patients were satisfied with GA Depot treatment at visit 16 and visit 29, and a significant improvement from visit 16 was assessed by the percent change in the global satisfaction domain (mean percent change 3.45, p = 0.0202).

CONCLUSIONS

Patient reported outcomes remained stable or improved during the OL period for all patients treated with GA Depot. The high treatment satisfaction (>90% of subjects satisfied with treatment) and the safety observed in the OL period confirm GA Depot's favorable safety and tolerability profile established in the PC period, positioning GA Depot as a safe and convenient treatment option that may increase treatment adherence in RMS patients.

Disclosures: Aaron Miller is the Coordinating PI of the study. Laura Popper, Nadav Bleich Kimelman, Shai Rubnov (co-inventor of GA Depot) and Uri Danon are employed by Mapi Pharma. Ehud Marom is a co-inventor of GA Depot, and founder and CEO of Mapi Pharma. Hadar Kolb is an external consultant to Mapi Pharma.

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