GA Depot (Long-acting IM Injection of Glatiramer Acetate) Presents Improved Safety and Tolerability Features: Results from a Multinational, Double-blind, Placebo-controlled Phase 3 Study in Subjects with Relapsing Forms of Multiple Sclerosis

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Background

Multiple sclerosis (MS) is a chronic disease requiring lifelong therapy. GA Depot is a novel extended-release formulation in development containing glatiramer acetate (GA) and administered intramuscularly every 28 days. GA Depot significantly reduced the ARR and MRI activity in patients with relapsing forms of Multiple Sclerosis (RMS) in a double-blind, randomized, placebo-controlled (PC) phase 3 study.

Objective

To compare GA Depot's safety and tolerability to Copaxone's® published data on injection site reactions (ISRs), serious adverse events (SAEs) and immediate post injection reactions (IPIRs), defined as a constellation of symptoms that may occur within seconds to minutes after the injection and include at least 2 of the following: flushing, chest pain, palpitations, tachycardia, anxiety, dyspnea, constriction of the throat, and urticaria.

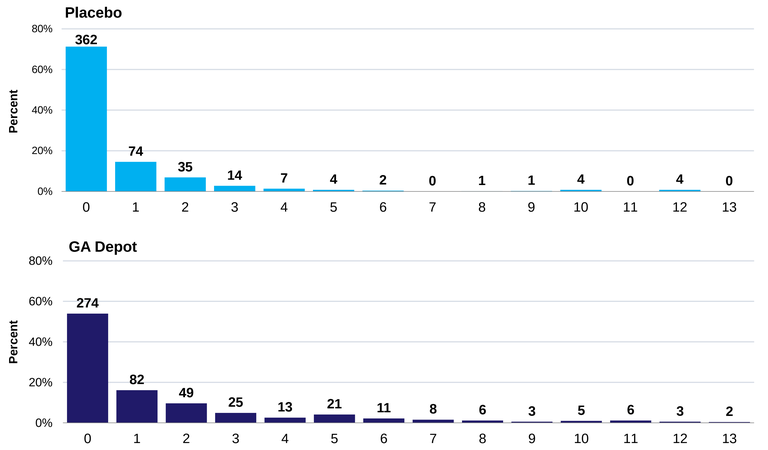
Design/Methods

GA Depot SAEs and ISRs yearly event rates were calculated using the data collected during the 1st treatment year with GA Depot in the placebo-controlled period of the phase 3 study and the data for the 2nd treatment year with GA Depot collected during the open label period of the study. Data was compared with the annualized rate of ISRs from Copaxone®'s published GLACIER study data (a 4-month open-label study with published ISR rates for once daily and thrice-weekly Copaxone® adjusted for one year). The percentage of patients experiencing SAEs was compared to data published in the GALA study (one-year placebo-controlled phase 3 study with thrice weekly Copaxone®). IPIR incidence was compared to the data in Copaxone® US label.

Results

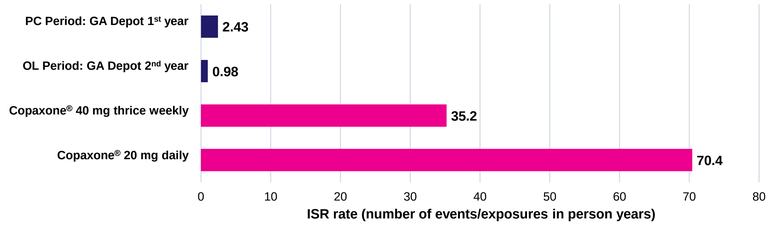
Most patients, 274 (53.9%) in GA Depot group did not report any ISR (Figure 1).

Figure 1: Histogram showing the distribution of the total number of ISR events by number of patients in the GA Depot and Placebo groups during the PC period of the study.



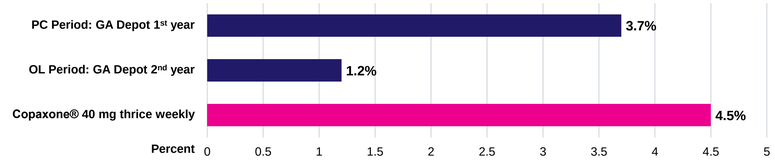
ISR rate (calculated as the number of events/exposure in person-years) was significantly lower with GA Depot in both the 1st and 2nd year of treatment than with Copaxone® once-daily or thrice weekly (Figure 2).

Figure 2: ISR rate with GA Depot and Copaxone®



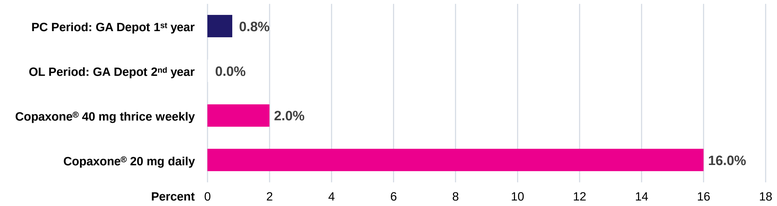
In patients treated with GA Depot, the incidence of SAEs (after excluding COVID-19 infection) in both the 1st and 2nd year of treatment was lower than in patients treated with Copaxone® 40 mg thrice weekly (Figure 3).

Figure 3: Incidence of SAEs (excluding COVID-19 infection) with GA Depot and Copaxone®



IPIR was significantly less frequent in patients treated with GA Depot compared to patients treated with Copaxone® 20 mg daily or Copaxone® 40 mg thrice weekly (Figure 4).

Figure 4: Incidence of IPIR with GA Depot and Copaxone®



Conclusions

Overall, GA Depot shows a favorable safety and tolerability profile compared to daily or thrice weekly use of GA formulation (Copaxone®). These advantages are expected to increase patient adherence and improve patients' quality of life.

Study Sponsored by Mapi Pharma Ltd

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.