Results of a Phase III, Multinational, Double Blind, Placebo-Controlled Study in Subjects with Relapsing Forms of Multiple Sclerosis to Assess the Efficacy, Safety and Tolerability of GA Depot, a Long-Acting IM Injection of Glatiramer Acetate, Administered Once Every Four Weeks

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Background

GA Depot (Glatiramer Acetate Depot) consists of extended-release microspheres administered intramuscularly once every 28 days.

Objective

To evaluate the efficacy, safety, and tolerability of GA Depot compared with placebo in patients with relapsing forms of multiple sclerosis (RMS).

Design/Methods

- GA Depot vs. Placebo, once every 4 weeks injections X52 weeks
- N=1016; 1:1 randomization
- Eligibility:
 - Relapsing MS; EDSS ≤5.5
 - Relapses: ≥1 in the previous year or ≥2 relapses in previous 2 years
- Primary endpoint: annualized relapse rate
- Key secondary endpoints: MRI
- Optional open label extension

Results

- GA Depot reduced annualized relapse rate at 52 weeks by 30.1% (P=0.0066) (Figure 1)
- GA Depot significantly reduced contrast enhanced lesions (P=0.0083) (Figure 2)
- GA Depot significantly reduced new or enlarging T2 hyperintense lesions (P=0.0305) (Figure 3)
- Mean EDSS significantly lower at 52 weeks (P=0.0191)
- Most subjects did not report injection site reactions 53.9% (Figure 4)
- 93.4% of subjects completing 52-week randomized portion of trial entered open label extension

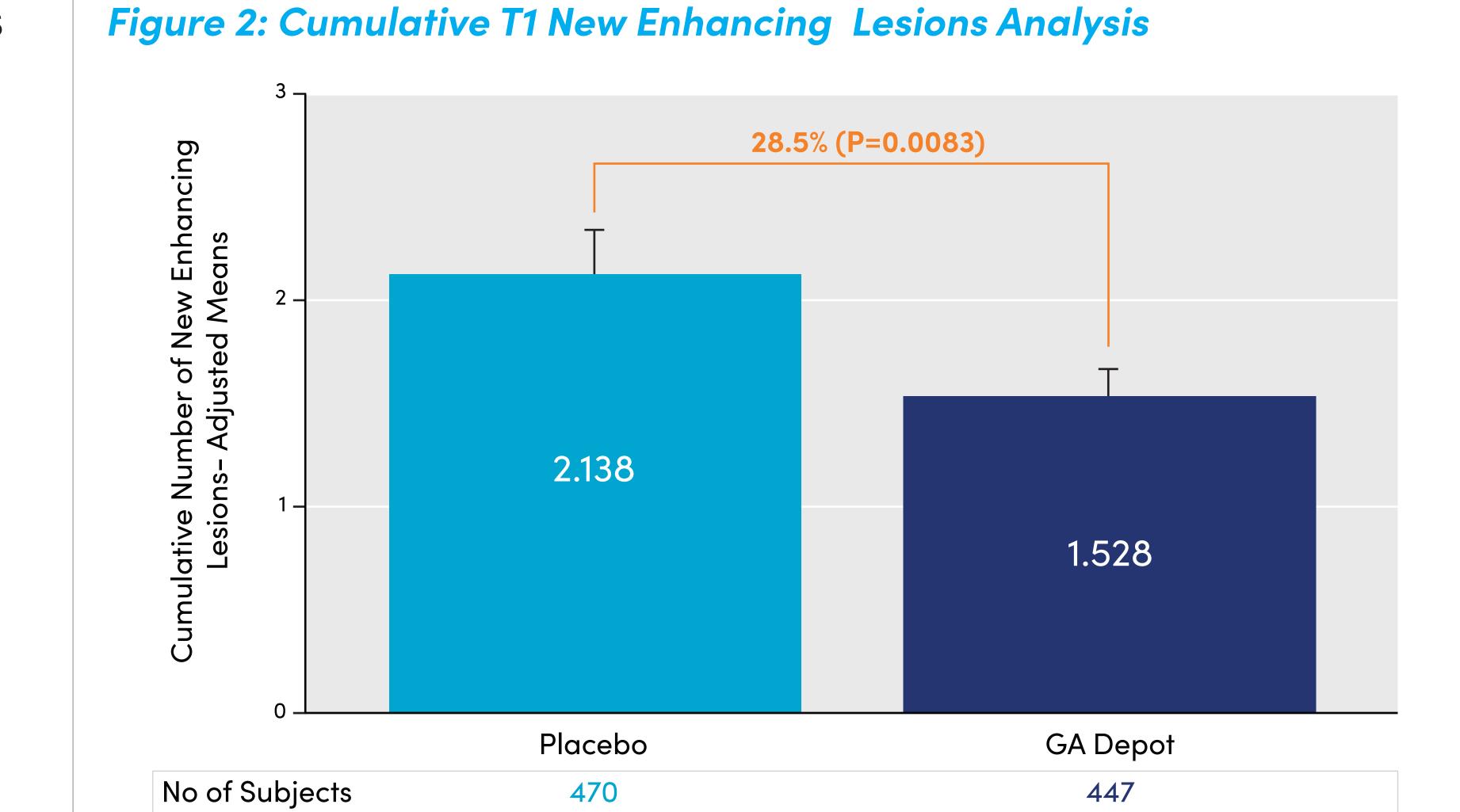


Figure 2: 1st Secondary endpoint analysis of cumulative T1 Gad Enhancing Lesions shows a statistically significant (P=0.0083) reduction of 28.5% in the average rate of cumulative T1 Gad Enhancing lesions between GA Depot vs Placebo.

Figure 3: New or Newly Enlarging Hyperintense T2 Lesions Analysis

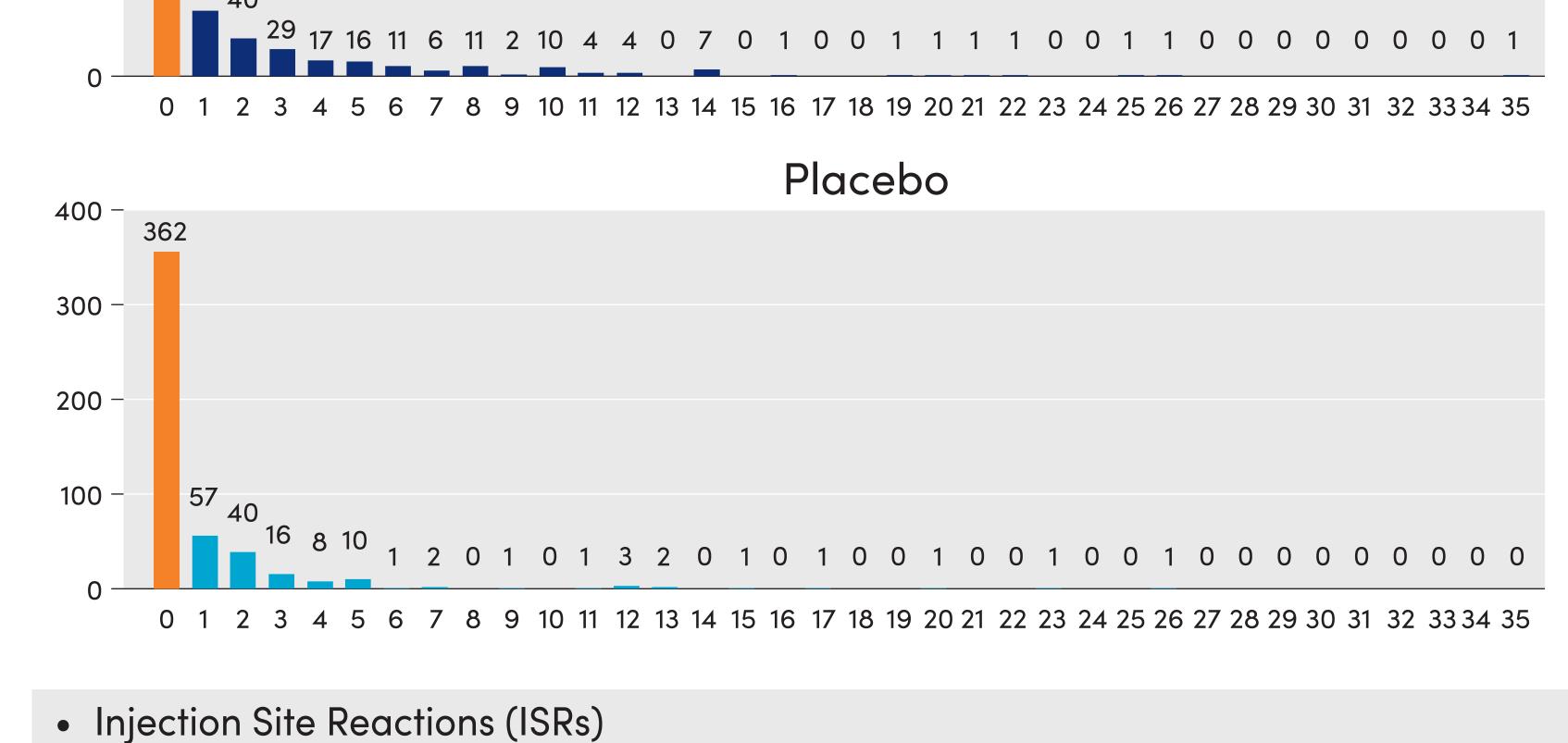


Figure 4: Histogram of Number of ISR Reports Per Subject During PC Period

- 274 subjects (out of 508 enrolled, 53.9%) did not report any ISR

69 (29.5%) reported only 1 ISR event

40 (17.1%) reported only 2 ISR events

Sharply declining afterwards

- Number of subjects is presented for each bar
- A subject may have more than one event on the same date

Figure 1: Annualized Relapse Rate Analysis

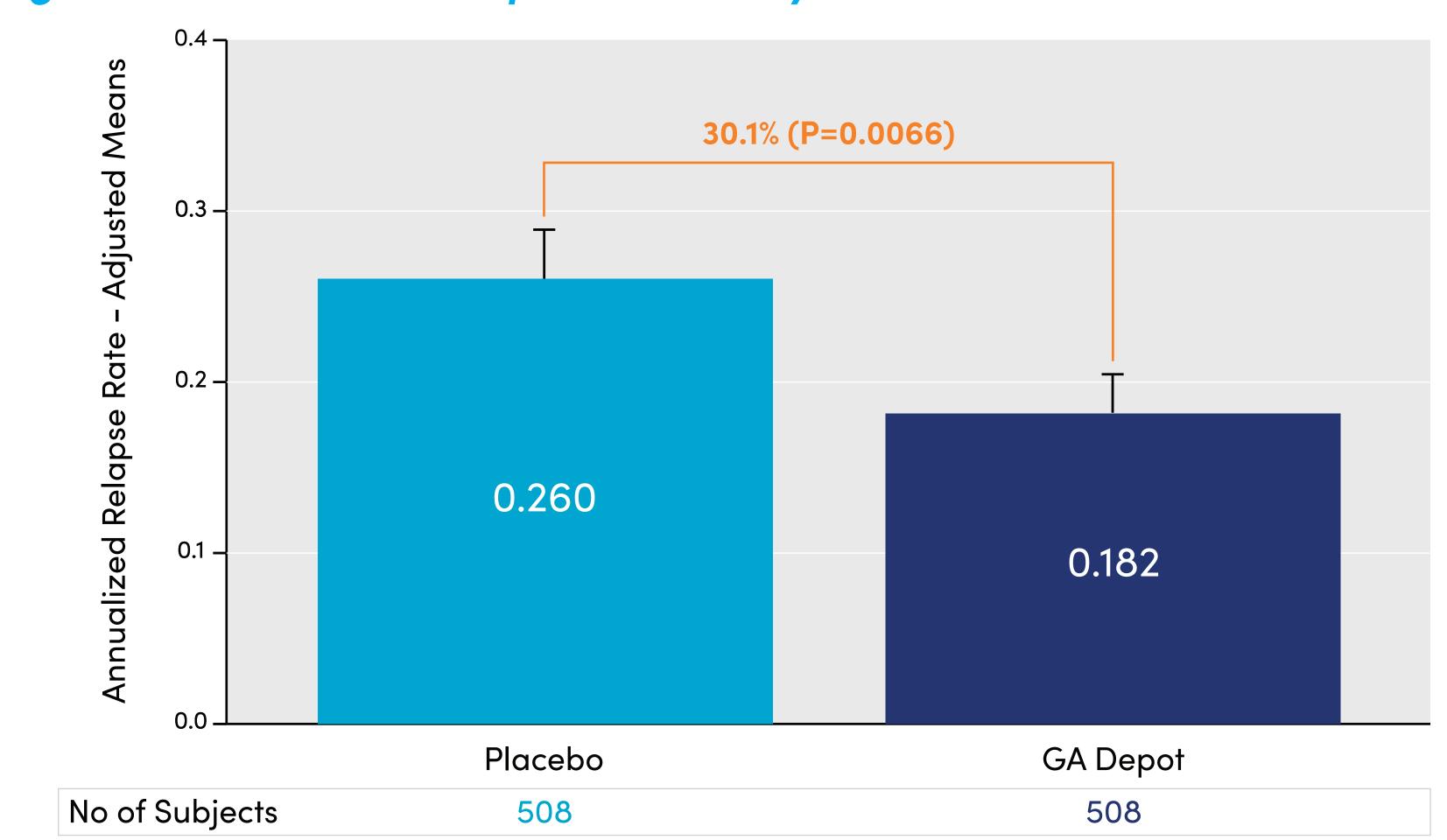


Figure 1: Primary Endpoint Analysis shows a statistically significant (P=0.0066) reduction of 30.1% in the risk for protocol defined relapse between GA Depot vs Placebo.

17.3% (P=0.0305) 4.527 3.743 **GA** Depot Placebo

Figure 3: 2nd Secondary endpoint analysis of New or Newly Enlarging Hyperintense T2 Lesions showed statistically significant (p= 0.0305, post hoc analysis) reduction of 17.3% for GA Depot subjects.

No of Subjects

Conclusions

GA Depot offers a safe and effective treatment for RMS, with a preferable schedule and with expected fewer Injection Site Reactions (ISRs) than other GA products. As with other depot regimens, fewer injections and associated ISRs are expected to improve patient satisfaction, compliance, and overall patient experience.

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. Prasanna C Ganapathi is employed by Viatris. Joseph Berger is the Chairman of the Data Monitoring Committee of the study. Hadar Kolb acts as the Coordinating PI for phase II with GA Depot. Ehud Marom is a co-inventor of GA Depot, and founder and CEO of Mapi Pharma.