Glatiramer Acetate Depot (Extended-Release) Phase IIa Study in Patients with Relapsing Remitting Multiple Sclerosis: Safety, Tolerability and Efficacy (No Evidence of Disease Activity) Subpopulation Four-Years Analysis

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Objective:
Safety, tolerability and efficacy assessment by NEDA-3 defined as: no relapses, no 12-week confirmed disability progression, no new T2 lesions and no gadolinium-enhancing lesions on MRI in the subpopulation of 10 RRMS patients treated with Glatiramer Acetate (GA) Depot who completed the core study and continued through three years of the study extension.

Background:
Improvement of treatment adherence remains an unmet need. Glatiramer acetate (GA) long-acting injection (GA Depot consists of extended-release microspheres containing GA, administered intramuscularly once every 28 days. Results of GA Depot phase IIa one-year core study and three years extension period in relapsing remitting MS (RRMS) suggest that GA Depot is safe, tolerable and efficacious.

Design/Methods:
Eligibility criteria included: age 18-70 years, diagnosis of RRMS and treatment with Copaxone® for ≥12 months prior to enrollment. Patients received monthly GA Depot at doses of 80mg or 40mg in the core study and 40mg in the study extension.

Results:

Adverse events (AEs) mainly included mild injection site reactions. No unexpected AEs were reported. The number of AEs was significantly reduced during the extension study compared to the core study, and during the fourth year compared to the first two years of the study. No systemic immediate post-injection reactions were detected. Patients received all injections as per protocol. Data analyzed by intention to treat population (mITT) (n=10): Mean EDSS score after four years showed no change compared to baseline. No Relapses or MRI activity was noted during that period. Four years NEDA-3 was achieved by 90% of the per protocol population.

Conclusions:

Encouraging results of the GA Depot four-year study support its long-term safety, tolerability, and efficacy in this study cohort. It further supports the assumption of GA Depot's potential to improve MS treatment by significantly reducing frequency of injections, increasing adherence and providing a therapeutic benefit.

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