Glatiramer Acetate Depot (extended-release) phase IIa study in patients with Primary Progressive Multiple Sclerosis: safety and efficacy snapshot

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Objective:
Assess the safety and efficacy data of GA Depot treatment (for up to 112 weeks) in eleven primary progressive MS (PPMS) subjects enrolled out of the 24 planned.

Background:
PPMS is characterized by worsening neurologic function from the onset of symptoms, without early relapses or remissions. GA long-acting injection (GA Depot) consists of extended-release microspheres containing GA, administered intramuscularly (IM) once every 28 days. Results of GA Depot phase IIa for four years in relapsing remitting MS suggest that GA Depot is safe, tolerable and efficacious. The IM administration together with the slow release formulation may result in a noted effect on PPMS patients as well.

Design/Methods:
Eligibility criteria included: age 18-65 years, subjects diagnosed with PPMS with signs of rapid disease progression (rate of ≥ 1 point increase / year on EDSS score) in the year prior to screening, EDSS score of ≥2.0 and ≤ 6.5 at baseline. Patients are receiving GA Depot IM at a dose of 40 mg every 28 days. Safety assessed by analysis of adverse events (AEs), CBC and blood chemistry. Efficacy is assessed by EDSS, 9HPT, T25FW tests, as well as by MRI analysis.

Results:
AEs were mainly mild. Most common AEs included injection site reactions and general weakness. No unexpected AEs were reported. Two SAEs were reported (one related and one not related to study drug). EDSS score remained stable for all patients and no 12 weeks confirmed disability progression (CDP) was detected. Mean 9HPT score and T25FW remained stable. MRI analysis (compared to baseline) revealed findings in three out of the 11 patients' population.

Conclusions:

These data snapshot suggest that GA Depot is possibly a safe and effective treatment for patients with PPMS, as demonstrated by stable mean: EDSS, 9HPT and T25FW data, which encourage us to continue this investigation.

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