Long-Term Efficacy Including Clinical NEDA and Safety of Three-Times-Weekly Dosing Regimen Of Glatiramer Acetate: 7-Year Results of the Glatiramer Acetate Low-Frequency Administration (GALA) Open-Label Extension Study

Short title for mobile app: 7-Year Results of the GALA Study
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Background: The GALA study showed glatiramer acetate 40 mg/mL 3 times weekly (GA40) significantly reduced the annualized relapse rate (ARR) by 34% and MRI activity by 34.7% versus placebo in patients with relapsing multiple sclerosis.

Objective: To describe the effects of early start (ES) and delayed start (DS) GA40 for up to 7 years.

Design/Methods: After the placebo-controlled (PC) phase, patients could enroll in an open-label extension (OLE) of GA40, in which ES patients continued on GA40, and DS patients switched from placebo to GA40. ARR was the primary endpoint. For efficacy outcomes, data from randomization to last available observation were evaluated. For safety, only GA40 exposure was considered.

Results: Of the 1404 patients enrolled in the PC phase, 834 ES and 419 DS patients continued into the OLE phase. 580 (69.5%) ES and 261 (62.3%) DS patients completed the OLE study. The overall intent-to-treat population median GA exposure and follow-up were 4.9 and 5.5 years, respectively.

Overall, for ES and DS patients, ARR was 0.26 and 0.31, respectively (RR: 0.83; 95% CI: 0.700–0.993; *P*=0.0409). The percentage of patients without relapse was 48.1% and 44.0%, respectively. ES treatment prolonged the median time from randomization to first relapse (4.9 years) versus DS (4.3 years; HR: 0.82; 95% CI: 0.693–0.959; *P*=0.0135). The percentage of patients without 6-month confirmed disability progression (CDP) was 81.9% and 81.3%, respectively. A post hoc analysis of NEDA2 (no relapse, no 6-month CDP) showed 49.3% of ES and 46.2% of DS patients were free of clinical disease activity.

The most common adverse events, injection-site reactions and immediate post-injection reactions, were generally mild.

Conclusions: The 7-year safety profile of GA was consistent with prior studies, with no new or unexpected adverse events. GA40 treatment was associated with low ARR and 6-month CDP in ES and DS patients.

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Disclosures:
P.R. was the co-PI international for the GALA study.

J.A. reports personal fees as an employee of Teva Pharmaceuticals.

S.K. is a former employee of Teva Pharmaceuticals, Netanya, Israel, and reports personal fees for consulting for Teva Pharmaceuticals.

S.R. reports personal fees as an employee of Teva Pharmaceuticals, Netanya, Israel.

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