To date, Multiple Sclerosis (MS) cannot be cured and, as a chronic disease, MS requires lifelong therapy for which adherence is still a major challenge. While several disease-modifying treatments have been developed and approved for MS, still, unmet need remains to improve patient outcomes, by improving treatment efficacy, tolerability and adherence. Glatiramer acetate (GA) long-acting injection (GA Depot) consists of microspheres containing GA, which is released from its formulation continuously over 30 days. In vivo data generated in MOG-EAE mice model (Myelin Oligodendrocyte Glycoprotein - Experimental Autoimmune Encephalomyelitis), has shown that GA Depot is as effective as Copaxone® in ameliorating EAE symptoms (Fig 1).

**RESULTS**

Twenty-five RRMS patients were enrolled as follows: 80mg dose (n=12) and 40mg dose (n=13). Overall, 72% of study population were female, mean MS duration was 15.5±8.3 years and mean EDSS score was 2.4±1.6, at baseline. Adverse events (AEs) mainly included mild injection site reactions (ISRs) and no unexpected AEs were reported. Statistically significant fewer ISRs were reported with the 40mg dose than with the 80mg dose. No immediate post-injection reactions, as recorded with GA (Copaxone®), were detected. Two relapses were recorded during treatment with Copaxone®, within 12 months prior to study enrollment; one relapse with no changes in EDSS score was recorded during the study. No changes in the mean EDSS score were recorded per protocol (PP) population. Above 92% of the PP population showed no changes (no new lesions nor newly enhancing lesions) in 12 months’ MRI scans compared to baseline.

A composite outcome: No Evidence of Disease Activity (NEDA), defined as no relapses, no 12-week confirmed disability progression and no new lesions or no gadolinium-enhancing lesions, was achieved by 84.6% of the patients (PP population) in this GA Depot phase II one-year trial (Fig 2).

**CONCLUSIONS**

The GA Depot small cohort one-year results support the assumption of its potential to improve MS treatment by significantly reducing number of injections, increasing adherence and providing a therapeutic benefit. GA Depot’s safety, tolerability and encouraging efficacy data prompts the continuation to one phase III pivotal trial.