

Study Endpoints

- The primary endpoint was the annualized rate of IRAEs, i.e. the total number of events occurring during the extension phase per patient-year of drug exposure during the extension phase
 - Assessments of IRAEs (including all local injection-site reactions [ISRs] or events related to immediate post-injection reaction) were performed during the extension phase based on the patient's diary card recordings of occurrence and severity
 - Severity was defined as shown in **Box 1**
 - All IRAEs occurring in the active treatment phase were coded to MedDRA preferred terms
- The secondary endpoint was change in assessment of patient perception of treatment convenience, using the convenience-specific subscale (items 4–6) of the VAS as measured every 4 months from extension phase baseline (**Box 2**)
 - Higher scores represented more positive perceptions of treatment
- Additional endpoints included the rate of ISRs, subject-reported impact on psychological well-being using the Multiple Sclerosis Impact Scale-29 questionnaire, and subject perceptions of overall satisfaction using the TSQM-9 subscale (item 1)

Study Methodology

- The last observed post-baseline data were used for endpoint visit analysis during the extension phase
 - For patients who withdrew from the study, data at the ET visit were included in endpoint visit analysis, with the exception of MSIS-29 and TSQM-9 questionnaires for which the ET visit was considered as the next scheduled visit

Acknowledgments This study was funded by Teva Pharmaceutical Industries Ltd, Petach Tikva, Israel. We thank the patients and study staff; Robin Everts (of Teva Pharmaceuticals) for assistance with study conduct and statistical analyses; and Rhonda Charles, PhD (Chameleon Therapeutics) for assistance with funding from Teva Pharmaceutical Industries) and Peter Feldman, PhD (Teva Pharmaceuticals) for editorial assistance.

Disclosures **Daniel Wynn** has received compensation for speaking and/or consulting from Acorda Therapeutics, Avanir Pharmaceuticals, GlaxoSmithKline, Pfizer, Sanofi/Genzyme, Teva, and Xenoport, and has received research support from Acorda Therapeutics, Avanir Pharmaceuticals, Serono, GlaxoSmithKline, Novartis, Ono, Osmotica, Receptos, Roche, Sanofi/Genzyme, Xenoport, Teva, and the National MS Society.

Scott Kolodny, **Svetlana Rubinchik**, **Joshua R. Steiner**, and **Augusto Grinspan** are employees of Teva Pharmaceutical Industries.

Jerry S. Wolinsky has received compensation for service on steering committees or data monitoring boards for Novartis, Roche, Sanofi, and Athersys, Genzyme, Novartis, Roche, RND, Teva, and Xenoport; has received royalty payments through the University of Texas Health Science Center at Houston for monoclonal antibodies out-licensed to Chemicon International; and has received research support from Genzyme, Sanofi, and the National University of Texas Health Science Center at Houston.