Five-Year Safety and Efficacy of Golimumab in Patients With Active Rheumatoid Arthritis Despite Previous Anti-Tumor Necrosis Factor Therapy: Final Study Results of the Phase 3, Randomized, Placebo-Controlled GO-AFTER Trial


Medical University of Vienna and Hospital City Center, Vienna, Austria; University of Massachusetts Medical School, Worcester, MA, USA; Academic Medical Center/University of Amsterdam &主义思想 Medical Center Heerlen, the Netherlands; NYU Langone Clinic, Rochester, MN, USA; Arthritis & Rheumatic Disease Specialties, Aventura, FL, USA; Hôpital Eber, Hamburg, Germany; Alnatura Center of Clinical Research, Dusseldorf, PA, USA; Janssen Global Services, LLC; Janssen Research & Development, LLC; Spring House, PA, USA; University of Pennsylvania, Philadelphia, PA, USA

Background

GO-AFTER was the first multicenter, randomized, placebo (PBO)-controlled trial of the safety/efficacy of anti-TNF agent, golimumab (GLM) in patients who were ineffectively treated with TNF inhibitor therapy. Herein, we report the findings of the five-year follow-up of GO-AFTER.

Objective

The primary objective of the study was the safety and efficacy of GLM through 5 years.

Methods

Patients were randomized to receive GLM 50 mg or 100 mg after baseline washout and treatment with PBO. Study drug initiation was allowed after the Week 24 database lock. Long-term analyses were analyzed using observed data, and thus, the data presented therein reflects the natural history of the study. Of 388 patients with available samples, 31 (8.0%) tested positive for antibodies to GLM.

Results

Of 388 patients with available samples, 31 (8.0%) tested positive for antibodies to GLM. As with all long-term analyses, there are limitations to these data. All patients received GLM 50 mg after Week 24, and therefore there is no control group beyond Week 24. The study was open label after the Week 24 DBL. Long-term analyses were analyzed using observed data, and thus, the data presented therein reflects the natural history of the study. The study was supported by Janssen Research & Development, LLC.

Conclusions

Golimumab was maintained through 5 years among patients with ineffective RA who continued therapy.