

SUPPLEMENTAL ONLINE TEXT

Additional details regarding selection of the golimumab dosing regimen

Data derived from the golimumab clinical development program indicated that maintaining drug levels close to or above the trough serum golimumab concentrations resulting from subcutaneous golimumab 50 mg every 4 weeks are important for robust and sustained ACR responses. Also using data from the golimumab program, results of simulations indicated that intravenous golimumab 2 mg/kg + MTX every 8 weeks would be anticipated to yield trough steady-state concentrations (0.28 µg/mL) comparable to subcutaneous golimumab 50 mg every 4 weeks (0.30 µg/mL). Thus, golimumab 2 mg/kg + MTX every 8 weeks was chosen as the dosing regimen for the current GO-FURTHER trial.

Additional patient eligibility criteria

Patients who received treatment with disease-modifying antirheumatic drugs (DMARDs) other than methotrexate (MTX) or non-oral corticosteroids within the prior 4 weeks were excluded, as were patients with prior receipt of: any commercial/investigational TNF-inhibitor; natalizumab or other alpha-4-integrin blockers; or rituximab, abatacept, or efalizumab. Stable ongoing doses of NSAIDs and/or oral corticosteroids (≤ 10 mg/day prednisone/day or equivalent).

Eligible patients met all relevant tuberculosis (TB) and clinical laboratory screening criteria. With regard to TB, patients with no history of latent or active TB prior to screening, no signs or symptoms suggestive of active TB upon medical history and/or physical examination, no recent close contact with a person with active TB, a negative QuantiFERON-TB[®] Gold In-Tube

(Cellestis; Valencia, CA) test result within 6 weeks of study agent start, and a chest radiograph within 3 months prior to the first administration of study agent and read by a qualified radiologist. Patients with evidence of close contact to active TB or latent TB could enroll in the study if treated for latent TB prior to or simultaneously with the first administration of study agent.

Patients with other inflammatory diseases, a known hypersensitivity to human immunoglobulin proteins or other components of golimumab, or prior receipt of any commercial or investigational anti-TNF therapy were ineligible. Patients were also ineligible if they had a history of latent or active granulomatous infection, including histoplasmosis, or coccidioidomycosis prior to screening; had a bacille Calmette-Guérin vaccination within 12 months of screening; had a chest radiograph within 3 months prior to the first administration of study agent that showed an abnormality suggestive of a malignancy or current active infection, including TB; had a nontuberculous mycobacterial infection or opportunistic infection (e.g., cytomegalovirus, pneumocystosis, aspergillosis) within 6 months prior to screening; or had received, or was expected to receive, any live virus or bacterial vaccination within 3 months prior to the first administration of study agent, during the study, or within 6 months after the last administration of study agent.

Further, eligible patients had no history of an infected joint prosthesis, or receipt of antibiotics for a suspected infection of a joint prosthesis, if that prosthesis has not been removed or replaced; a serious infection (e.g., hepatitis, pneumonia, or pyelonephritis), hospitalization for an infection, or treatment of an infection with intravenous antibiotics within 2 months prior to the

first administration of study agent; a history of, or ongoing, chronic or recurrent (> 3 identical infections/12 months) infectious disease; an open, draining, or infected skin wound; or an ulcer.

Patients with a history of known demyelinating diseases such as multiple sclerosis or optic neuritis were excluded, as were patients with a history of, or concurrent, congestive heart failure. Patients with a history of lymphoproliferative disease, including lymphoma, or signs suggestive of possible lymphoproliferative disease such as lymphadenopathy of unusual size or location, or clinically significant splenomegaly were ineligible, as were patients with any known malignancy or a history of malignancy within the previous 5 years (with the exception of a treated nonmelanoma skin cancer with no evidence of recurrence).