



Golimumab Phase 3 Data Show Significant Improvement in Physical Function in Patients with Rheumatoid Arthritis

Findings Also Showed Patients Experienced Improvements in Quality of Life Measures and Fatigue Despite Treatment with Other Anti-TNFs or Methotrexate

SAN FRANCISCO, Calif., October 27, 2008 - Results from two Phase 3 studies showed that patients receiving every four week subcutaneous injections of golimumab (CNTO 148) 50 mg or 100 mg, an investigational therapy, experienced significant improvements in physical function, health-related quality of life (HRQOL) and fatigue. The data from the randomized, double-blind, placebo-controlled studies in patients with active moderate to severe rheumatoid arthritis (RA) were presented at the American College of Rheumatology (ACR) Annual Scientific Meeting. The first trial was in patients who were previously treated with anti-tumor necrosis factor (TNF) agents and the second study was in patients who were active despite ongoing treatment with methotrexate.

"In addition to reducing signs and symptoms, these data show improvement in important measures of functional ability and quality of life," said Jonathan Kay, M.D., Director, Clinical Trials, Rheumatology Unit, Massachusetts General Hospital; Associate Clinical Professor of Medicine, Harvard Medical School, and lead study investigator. "These data support the potential benefit of golimumab in patients previously treated with anti-TNF therapies or methotrexate."

In the study, GOLimumab After Former anti-TNF Therapy Evaluated in RA (GO-AFTER), 50 mg and 100 mg doses of golimumab were studied in patients who had active RA and who were previously treated with anti-TNF treatments, but where anti-TNF treatment had been discontinued due to lack of efficacy (58 percent), intolerance (17 percent) or other reasons (40 percent). Patients continued to receive stable doses of methotrexate, sulfasalazine and/or hydrochloroquine if they were receiving them at baseline.

Golimumab-treated patients who had discontinued previous anti-TNF treatment for any reason experienced significant improvements in physical function, as measured by the Health Assessment Questionnaire (HAQ). HAQ assesses the degree of difficulty a person has in accomplishing tasks in eight functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping and other activities of daily living).

At week 24, the proportion of patients experiencing clinically relevant improvement (increase in HAQ score of at least 0.25 from baseline) was significantly greater for golimumab-treated patients compared with those receiving placebo. More than half of patients in the combined golimumab group (52 percent) achieved the measure, compared with 34 percent of placebo-treated patients ($P < 0.001$). Also at week 24, patients receiving golimumab experienced a mean improvement in HAQ of 0.27 ± 0.51 , compared with an improvement of 0.05 ± 0.51 among patients receiving placebo ($P < 0.001$). Importantly, among patients whose prior anti-TNF therapy was discontinued due to lack of efficacy, golimumab-treated patients experienced a mean improvement of 0.23 ± 0.50 in HAQ, compared with an average improvement of 0.06 ± 0.51 for patients receiving placebo ($P < 0.05$).

At week 24, the combined golimumab group also experienced significantly greater mean improvement in fatigue, 6.8 ± 11.4 , compared with an improvement of 3.0 ± 9.7 among patients treated with placebo ($P < 0.001$). Patients were evaluated with the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), a 13-item questionnaire that assesses self-reported fatigue and its impact on daily activities and function.

Improvements Seen in Patients Previously Treated with Methotrexate

A second Phase 3 study also presented at ACR evaluated 50 mg and 100 mg doses of golimumab in RA patients who had active RA and were previously treated with methotrexate. In GOLimumab FOR subjects With Active RA Despite Methotrexate (GO-FORWARD), patients also indicated significant improvement in fatigue. At week 24, the mean improvement in FACIT-F was 7.2 ± 8.6 in the combined golimumab group, compared with an improvement of 2.2 ± 9.5 among patients receiving methotrexate alone ($P < 0.001$).

According to the Arthritis Foundation, in addition to joint pain and swelling, RA may make daily functioning difficult and is frequently associated with fatigue. "Patients with RA often say that fatigue is one of their most frustrating symptoms because it makes it difficult for them to participate in work or social activities," said Mark Genovese, M.D., professor of medicine at Stanford University School of Medicine, and lead study investigator. "A reduction in fatigue would represent a tremendous benefit and significantly impact the lives of patients with this disease."

Through week 24, patients in both dose groups receiving golimumab plus methotrexate experienced significant improvement in

physical function, compared with patients receiving methotrexate alone. At 24 weeks, 70 percent of those receiving golimumab plus methotrexate experienced a clinically relevant improvement in physical function, compared with 39 percent of patients receiving methotrexate alone ($P < 0.0001$). Also at week 24, the combined golimumab group achieved a mean improvement in HAQ of 0.46 ± 0.53 , compared with an improvement of 0.13 ± 0.58 among patients receiving methotrexate alone ($P < 0.001$).

Patients treated with golimumab also experienced significant improvement in HRQOL, as assessed by the Physical Component Summary (PCS) and Mental Component Summary (MCS) scores of the Short form (SF)-36 questionnaire. In the combined golimumab plus methotrexate group, the mean improvement in PCS at week 14 was 7.7 ± 8.1 , compared with an improvement of 2.5 ± 8.1 in the group receiving methotrexate alone ($P < 0.001$). Patients in the combined group also experienced a mean improvement in MCS of 3.1 ± 10.8 at week 24, compared with 0.8 ± 9.7 among patients receiving methotrexate alone ($P < 0.05$). The SF-36 is a 36-item questionnaire that assesses impact in eight areas: physical functioning, pain, vitality, social functioning, psychological functioning, general health perceptions and role limitations due to physical and emotional problems. Lower scores indicate poorer functioning and well-being.

The Biologics License Application (BLA) and Marketing Authorization Application (MAA) for golimumab were submitted earlier in the year and are currently under review by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), respectively. The filings are based on the extensive clinical development program for golimumab, including data from five pivotal Phase 3 trials in RA, psoriatic arthritis and ankylosing spondylitis.

About the GO-AFTER Trial

GO-AFTER was a Phase 3, multi-center, double-blind trial that included 461 patients with active RA of 8.65 years mean duration. All patients had previously received at least one anti-TNF agent, with 25 percent ($n=115$) having been treated with two therapies and 9 percent ($n=43$) with three. Discontinuation of previous anti-TNF therapy was due to lack of efficacy (58 percent), intolerance (17 percent) and other reasons (40 percent). Patients were randomized to one of three treatment groups: subcutaneous placebo, golimumab 50 mg or golimumab 100 mg every four weeks. At baseline, 66 percent of patients were receiving methotrexate; 5 percent and 7 percent of patients were receiving sulfasalazine and hydrochloroquine, respectively. Patients continued to receive stable doses of methotrexate, sulfasalazine and/or hydrochloroquine if receiving them at baseline.

Golimumab was generally well tolerated in this study. Through week 24, 72 percent, 66 percent and 78 percent of patients in the placebo, golimumab 50 mg and golimumab 100 mg groups, respectively, experienced at least one adverse event (AE). Ten percent of patients in the placebo group experienced serious AEs, compared with 7 percent and 5 percent of patients in the golimumab 50 mg and golimumab 100 mg groups, respectively. Serious infections were reported in 3 percent, 3 percent and 1 percent of patients, and injection site reactions (ISR) through week 16 occurred in 3 percent, 4 percent and 11 percent of patients in the placebo, golimumab 50 mg and golimumab 100 mg groups, respectively. The most commonly reported ISR was erythema, a redness of the skin due to inflammation. No serious or severe ISRs were reported, and none led to the discontinuation of patients in the study. Antibodies to golimumab were detected in 4 percent of golimumab-treated patients (50 mg and 100 mg).

About the GO-FORWARD Trial

GO-FORWARD, a Phase 3, multi-center clinical trial included 444 patients with active RA. Adult patients with more than four tender and swollen joints, despite methotrexate therapy, were randomly assigned to receive golimumab (50 or 100 mg) plus methotrexate, golimumab 100 mg plus placebo or placebo plus methotrexate at weeks 0, 4, 8, 12, 16 and 20. Data were assessed at weeks 14 and 24. The co-primary endpoints were percentage of patients achieving ACR 20 response at week 14 and improvement from baseline in HAQ at week 24.

Through week 24, 68 percent of patients in both the combined golimumab plus methotrexate groups and the placebo plus methotrexate group experienced at least one adverse event (AE). Nine percent of patients in the combined golimumab plus methotrexate groups experienced a serious AE compared with 4 percent of patients receiving placebo plus methotrexate. Three percent of patients in the combined golimumab plus methotrexate groups and 1 percent in the group receiving placebo plus methotrexate experienced serious infections. Rates of ISRs were 5 percent in the combined golimumab plus methotrexate groups and 3 percent in the group receiving placebo plus methotrexate. Two percent of golimumab-treated patients developed antibodies. Four patients participating in the study developed malignancies: one patient taking golimumab 100 mg plus methotrexate developed breast cancer, one patient taking placebo plus methotrexate developed Bowen's disease and squamous cell skin cancer, one patient taking golimumab 100 mg plus placebo developed basal cell cancer, and one patient taking golimumab 100 mg plus placebo developed squamous cell carcinoma. One patient receiving golimumab 100 mg plus placebo died from diarrhea, colitis and sepsis.

Anti-TNF therapies have been associated with serious and sometimes fatal risks including the risk of tuberculosis and other serious infections, malignancies, heart failure, central nervous system disorders, reactivation of hepatitis B and other serious events.

About Rheumatoid Arthritis

RA is a chronic and debilitating disease that affects approximately 1.3 million people in the United States and more than three

million people in Europe. Signs and symptoms of RA include pain, stiffness and motion restriction in multiple joints. Because RA is a progressive disease, it can cause permanent joint deformity and severe disability if not diagnosed early or if initial treatment is delayed. RA can occur at any age, but is most common in adults 30-50 years old and is two-to-three times more prevalent in women than in men. The cause of RA is unknown, although genetic factors may contribute to the disease.

About Golimumab

Golimumab, the next-generation human anti-TNF-alpha monoclonal antibody from Centocor Inc. and Schering-Plough Corporation, is currently in the most comprehensive Phase 3 development program to date for an anti-TNF-alpha biologic therapy. With ongoing studies for the treatment of RA, psoriatic arthritis and ankylosing spondylitis, golimumab is being studied as an every four-week subcutaneous injection and an IV infusion therapy. Golimumab targets and neutralizes both the soluble and membrane-bound forms of TNF-alpha.

Centocor discovered golimumab and has exclusive marketing rights to the product in the United States. Pending regulatory approval, Schering-Plough will assume exclusive marketing rights outside the United States except in Japan, Indonesia and Taiwan where golimumab will be co-marketed by Mitsubishi Tanabe Pharma Corporation and Janssen Pharmaceutical Kabushiki Kaisha; Hong Kong, where golimumab will be exclusively marketed by Janssen-Cilag; and China where golimumab will be exclusively marketed by Xian-Janssen.

About Centocor

Centocor is harnessing the power of world-leading research and biomanufacturing to deliver innovative biomedicines that transform patients' lives. Centocor has already brought innovation to the treatment of Crohn's disease, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, ulcerative colitis, pediatric Crohn's disease and psoriasis.

The world leader in monoclonal antibody production and technology, Centocor has brought critical biologic therapies to patients suffering from debilitating immune disorders. Centocor is a wholly-owned subsidiary of Johnson & Johnson.

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