Five-Year Data Demonstrate Long-Term Efficacy and Safety with ORENCIA® (abatacept) in Adults with Rheumatoid Arthritis Who had an Inadequate Response to Methotrexate

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- Data Presented at American College of Rheumatology Annual Meeting -

BOSTON--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that cumulative five-year data from an open-label long-term extension of a Phase IIb trial demonstrate the long-term efficacy and safety of ORENCIA® (abatacept) in adult rheumatoid arthritis (RA) patients who had an inadequate response to methotrexate (MTX). The data show that, in these patients, ORENCIA provided sustained improvements in ACR responses, physical function and health-related quality of life. These data, combined with the retention rates observed in this study, demonstrate that ORENCIA provides durable long-term clinical benefits in patients with active RA who had an inadequate response to MTX. Results of this study were presented at the 2007 American College of Rheumatology (ACR) Annual Scientific Meeting.

"Studying the long-term efficacy of a treatment is important because RA is a chronic disease," said Joel Kremer, M.D., Chief of Rheumatology, Albany Medical College. "These data are important because they show that ORENCIA is efficacious and has an acceptable safety profile over an extended period of time in patients with an inadequate response to methotrexate."

Details of the Study

Patients in the initial one-year, double-blind, placebo-controlled randomized trial received MTX and either ORENCIA (10 mg/kg or 2 mg/kg) or placebo administered as a 30-minute intravenous infusion on Days 1, 15 and 30, and every four weeks thereafter, in addition to MTX. The primary endpoint of the double-blind portion of the study was ACR 20 at 6 months (60 percent for ORENCIA® (abatacept) vs. 35.5 percent for placebo). All patients completing the double-blind period were eligible to continue in the open-label long-term extension, in which all participants received a fixed dose of ORENCIA approximating 10 mg/kg every four weeks, in addition to MTX. Efficacy, health-related quality of life and safety were assessed.

Of the 235 patients completing the double-blind period, 219 entered the long-term extension (ORENCIA 10 mg/kg=84; ORENCIA 2 mg/kg=68; placebo=67), and 130 (59.4 percent) continued in the trial for five years. Baseline RA characteristics for long-term extension patients were similar between groups at initial randomization (mean disease duration: 8.2 - 9.9 years).

Data included in this as-observed analysis were from the original group receiving a dose approximating 10 mg/kg of ORENCIA in the one-year double blind phase (n=115) through five years' total treatment (n=56). At Year 1, improvements in ACR 20, 50 and 70 responses were sustained (83 percent, 65 percent and 40 percent, respectively). At Year 5, improvements in ACR 20, 50 and 70 responses were sustained (83 percent, 65 percent and 40 percent, respectively). More than one-third of these patients achieved an ACR 70 response at Year 5.

Physical function and health-related quality of life were assessed using the modified Health Assessment Questionnaire Disability Index (mHAQ-DI) and Short-Form 36 (SF-36), respectively. Clinically meaningful improvement in physical function was observed in 54.8 percent of patients at Year 1 and 52.8 percent of patients at Year 5 (n=53). Improvements in health-related quality of life were also maintained at Year 5. The mean improvement from baseline in the physical component summary was 9.7 at Year 1 (mean score 40.6) and was stable at 9.7 at Year 5 (mean score 41.7). The mean improvement in the mental component was 6.1 at Year 1 (mean score 52.3) and 5.4 at Year 5 (mean score 50.8). Improvements in all individual component scores of the SF-36 were also observed at Year 1 and maintained at Year 5.

The safety analysis represents five years of cumulative data. This includes all patients who received at least one dose of ORENCIA during the one-year double-blind period and all patients who entered the open-label period who received at least one dose of ORENCIA plus all patients randomized to receive placebo (n=287). The incidence rates observed during the five-year cumulative period for serious adverse events (SAEs), infections, serious infections, malignancies and autoimmune events were consistent with both the double-blind period and the integrated safety summary, which is comprised of seven core RA studies representing approximately 8,400 patient years of exposure. The incidence rates for SAEs in the double-blind period, five-year cumulative period and the integrated safety summary were 20/100 pt-years, 18.9/100 pt-yrs and 15.4/100 pt-yrs, respectively. The incidence rates for infections in the double-blind period, five-year cumulative period and the integrated safety summary were 94.2/100 pt-years, 77.3/100 pt-yrs and 79.2/100 pt-yrs, respectively. The incidence
rates for serious infections in the double-blind period, five-year cumulative period and the integrated safety summary were 2.1/100 pt-years, 3.0/100 pt-yrs and 3.0/100 pt-yrs, respectively. The incidence rates for malignancies in the double-blind period, five-year cumulative period and the integrated safety summary were 2.1/100 pt-years, 1.5/100 pt-yrs and 1.3/100 pt-yrs, respectively. A total of 12 autoimmune disorders, the most frequent of which were psoriasis and cutaneous vasculitis, were reported in 12 patients in the cumulative study period.

During the five-year cumulative period, 32 patients (11.1 percent) discontinued due to SAEs. A total of five deaths occurred through five years of the study; all were considered to be unlikely related or unrelated to study medication.

About ORENCIA® (abatacept)

ORENCIA is indicated in the United States for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adults with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs, such as methotrexate or TNF antagonists. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. ORENCIA should not be administered concomitantly with TNF antagonists and is not recommended for use concomitantly with anakinra.

Dosing and Administration

ORENCIA is administered by a healthcare professional as a 30-minute intravenous infusion at a fixed dose based on body weight ranging from approximating 10 mg/kg at day 0, 2 weeks, 4 weeks, and every 4 weeks thereafter. Acute infusion-related reactions were experienced in nine percent of people treated with ORENCIA and in six percent of people treated with placebo. According to the full prescribing information, the most frequently reported infusion-related adverse events (1 percent to 2 percent) were dizziness, headache, and hypertension. In pivotal studies, premedications were not required. However, appropriate medical support measures for the treatment of hypersensitivity reactions should be available for immediate use in the event of a reaction.

Important Safety Information about ORENCIA® (abatacept)

Before receiving treatment with ORENCIA individuals should tell their doctor if they are taking a TNF blocker (e.g., Enbrel®, Humira®, Remicade®) to treat rheumatoid arthritis (RA). ORENCIA should not be taken with these medications because of a higher chance of getting a serious infection. Individuals should also tell their doctor if they are taking Kineret® to treat RA. ORENCIA should not be taken with Kineret. People taking ORENCIA should notify their doctor if they are taking any other medications including hormones, over-the-counter medicines, vitamins, supplements or herbal products.

Individuals should let their doctor know if they have any kind of infection including an infection that is in only one place of the body (such as an open cut or sore) or an infection that is in the whole body (such as the flu). Having an infection could increase the risk for serious side effects from ORENCIA. It is also important for individuals to let their doctor know if they have an infection that won't go away or a history of infections that keep coming back.

People who have had tuberculosis (TB), a positive skin test for TB, recent close contact with someone who has had TB or develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) should call their doctor right away. Before starting treatment with ORENCIA, a doctor may examine the individual for TB or perform a skin test.

In addition, individuals should let their doctor know if they are scheduled to have surgery or any vaccination or have recently received a vaccination. People should inform their doctor if they have a history of chronic obstructive pulmonary (lung) disease (COPD). Taking ORENCIA® (abatacept) may cause COPD symptoms to get worse.

People who have diabetes and use a blood glucose monitor to check their sugar levels should tell their doctor. The infusion of ORENCIA contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day the infusion is received. The doctor may recommend a different monitor.

Women who are pregnant, planning to become pregnant or are thinking about becoming pregnant should tell their doctor. It is not known if ORENCIA can harm an unborn baby. Women who are breast-feeding should also inform their doctor. They will need to decide to either breast-feed or receive treatment with ORENCIA® (abatacept), but not both.

Like all medicines that affect your immune system, ORENCIA can cause serious side effects. The possible serious side effects include serious infections and allergic reactions. Also, rare cases of certain kinds of cancers have been reported.

People taking ORENCIA are at increased risk for developing infections including pneumonia, and other infections caused by viruses, bacteria, or fungi. Individuals should call their doctor immediately if they feel sick or get any infection during treatment with ORENCIA.

Allergic reactions are usually mild or moderate, generally occur within the first 24 hours of an infusion, and include hives, swollen face, eyelids, lips, tongue, throat, or trouble breathing. There have been some serious allergic reactions reported in people that received an infusion of ORENCIA.

There have been rare cases of certain kinds of cancer in people receiving ORENCIA. The role of ORENCIA in the development of cancer is not known.

The more common side effects with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea.


Bristol-Myers Squibb Company is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.

* Based on the percentages of patients achieving ACR 20, 50 and 70 responses, indicating 20 percent, 50 percent and 70 percent improvements in ACR criteria, respectively.