ORENCIA(R) (abatacept) Provided an Increasing Degree of Inhibition of Structural Damage Through Three Years in Adults with Moderate to Severe Rheumatoid Arthritis

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Three-Year Data from the AIM Trial Presented at the Annual Congress of the European League Against Rheumatism (EULAR)

PARIS--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced results of radiographic analyses from the AIM (Abatacept in Inadequate responders to Methotrexate) study, which demonstrated that ORENCIA® (abatacept) provided an increasing degree of inhibition of structural damage through three years of treatment in adult patients with moderate-to-severe rheumatoid arthritis (RA) who have had an inadequate response to methotrexate (MTX). The durability of effect was maintained throughout the study period, and an increasing degree of inhibition with ORENCIA plus MTX was observed in the first year through Year 2 and Year 3, which was consistent with scoring of both joint erosion and joint space narrowing. These data were presented at the Annual Congress of the European League Against Rheumatism (EULAR).

"Rheumatoid arthritis is a serious, chronic condition that worsens over time," said Joel Kremer, M.D., Pfaff Family Professor of Medicine, Albany Medical College. "Identifying long-term therapies that not only inhibit radiographic progression of the disease, but do so over an extended period of time, is critical to effectively treat this patient population."

Progressive structural damage from RA is associated with increasing disability over time. In the AIM study, a phase III, randomized, double-blind, placebo-controlled trial, the effects of long-term treatment with ORENCIA on radiographic outcomes were assessed over time in the open-label extension phase of the study.

Study Design and Findings

During the double-blind period of this study, 433 patients who had an inadequate response to MTX received a fixed dose of ORENCIA® (abatacept) (approximating 10 mg/kg, based on weight range) plus MTX or placebo in addition to background MTX, on Days 1, 15 and 29 and every four weeks thereafter for one year. Patients completing the double-blind phase were eligible to enter the open-label, long-term extension phase and received a dose of approximately 10 mg/kg ORENCIA plus MTX every 28 days. During the study, radiographs of hands and feet were performed at baseline and Years 1, 2 and 3, or upon early termination.

Radiographic assessment for total score (TS), joint space narrowing score (JSN) and erosion score (ES) were performed using the Genant-modified Sharp scoring method. Radiographs from baseline to Years 1, 2 and 3 were all re-read at Year 3 by two independent expert readers blinded to the original treatment allocation and the sequence of films. For patients who did not complete the study, radiographs were taken at the time of discontinuation and data were imputed for up to one year using linear extrapolation of the scores.

Of the 433 patients initially randomized to ORENCIA plus MTX, radiographs were available at baseline and at the end of Years 1, 2 and 3 from 70 percent of these patients (n=302). The mean change in TS, JSN and ES were 0.89, 0.35 and 0.53 units from baseline to Year 1, respectively; 0.43, 0.18 and 0.25 units from Year 1 to Year 2, respectively; and 0.25, 0.12, 0.14 units from Year 2 to Year 3, respectively. Significant changes in total score values at Year 3 relative to Year 2 were observed, p-value equal to 0.022. The approximate 50 percent reduction in all scores in Year 2 relative to Year 1 in this study confirms findings from a previously reported two-year analysis.

Of the 304 patients with evaluable radiographs at Year 1, 139 (45.7 percent) had no progression from baseline. Of the 135 patients who had no progression from baseline through Year 1, 92 (68.1 percent) who remained non-progressors through Year 2 continued to be non-progressors through Year 3.

In this study, the safety and tolerability profile of ORENCIA plus MTX through three years in patients with moderate to severe RA was consistent with the double-blind period. In the double-blind period of the AIM trial, the incidence of serious adverse events was 15.0 percent for ORENCIA and 11.9 percent for placebo. The most serious adverse reactions were serious infections (2.5 percent for ORENCIA and 0.9 percent for placebo) and malignancies (0.5 percent for ORENCIA, abatacept and 0.0 percent for placebo). The average incidence of adverse reactions was 97.3 percent for ORENCIA and 84.0 percent for placebo. The most frequently reported adverse reactions (greater than or equal to 5 percent) for ORENCIA...
included headache, nasopharyngitis and nausea. The most frequently occurring serious adverse events with ORENCIA were musculoskeletal, primarily related to hospitalizations for RA flares or elective surgery for RA. Discontinuation due to adverse reactions for ORENCIA and placebo was 4.2 percent and 1.8 percent, respectively. ORENCIA should not be given with an anti-tumor necrosis factor antagonist and is not recommended for concomitant use with a biologic DMARD.

About ORENCIA® (abatacept)
ORENCIA is a prescription medicine that is used to treat adults with moderate to severe rheumatoid arthritis (RA) including those who have not been helped enough by other medicines for RA. ORENCIA may prevent further damage to bones and joints, and may help the individual's ability to perform daily activities. In adults ORENCIA may be used alone or with disease-modifying anti-rheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

ORENCIA also reduces signs and symptoms in children and adolescents 6 years of age and older with moderate to severe polyarticular juvenile idiopathic arthritis (JIA). In children and adolescents ORENCIA may be used alone or with methotrexate (MTX).

ORENCIA should not be used with TNF antagonists and is not recommended for use with other biologic rheumatoid arthritis therapy, such as anakinra.

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) is a systemic, chronic, autoimmune disease characterized by inflammation in the lining of joints (or synovium), causing joint damage with chronic pain, stiffness, swelling and fatigue. RA causes limited range of motion and decreased function as a result of affected joints losing their shape and alignment.

RA affects about one percent of the world's population, including more than one million people in the United States. The condition is more common in women than in men, who account for 75 percent of patients diagnosed with RA. ORENCIA is one treatment option indicated in adult patients with moderately to severely active RA. ORENCIA may be used as monotherapy or concomitantly with DMARDs other than tumor-necrosis factor (TNF) antagonists. ORENCIA® (abatacept) is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

Important Safety Information About ORENCIA
Before receiving treatment with ORENCIA, a lyophilized powder for intravenous infusion, individuals should tell their doctor about all their medical conditions, including if they have any kind of infection even if it is small (such as an open cut or sore) or an infection that is in the whole body (such as the flu) or have an infection that will not go away or a history of infections that keep coming back. People should tell their doctor if they have had tuberculosis (TB), a positive skin test for TB, or recent close contact with someone who has had TB. If symptoms of TB occur (a dry cough that doesn't go away, weight loss, fever, night sweats), they should call their doctor right away. Before starting treatment with ORENCIA, a doctor may examine the person for TB or perform a skin test.

Individuals who have or have had viral hepatitis should tell their doctor. The doctor may want to examine them for hepatitis before using ORENCIA. People should inform their doctor if they have a history of chronic obstructive pulmonary (lung) disease (COPD). In addition, individuals should let their doctor know if they are scheduled to have surgery or recently received a vaccination or are scheduled for any vaccination.

People should also let their doctor know if they are allergic to any of the following ingredients in ORENCIA: abatacept, maltose, monobasic sodium phosphate, or sodium chloride for administration. People who have diabetes and use a blood glucose monitor to check your 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 of the infusion. The doctor may tell them to use a different way to monitor their blood sugar levels.

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 your 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, but not both.

People taking ORENCIA should notify their doctor if they are taking any other kinds of medicine, including prescription and nonprescription medicines, vitamins, and herbal supplements. It is also important for individuals to tell their doctor if they are taking other biologic medicines to treat RA or JIA such as: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra) or Rituxan® (rituximab). You may have a higher chance of getting a serious infection if you take ORENCIA® (abactept) with other biologic medicines.

Possible Side Effects of ORENCIA® (abatacept)
ORENCIA can cause serious side effects including serious infections. People receiving ORENCIA have a higher chance of getting 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 of the following signs of infection: fever, feel very tired, cough, feel flu-like, or warm, red or painful skin.

Allergic reactions can happen on the day of treatment or the day after receiving ORENCIA. People should tell their doctor or get emergency medical help right away if they have hives, swollen face, eyelids, lips, tongue, throat, or trouble breathing.

Certain kinds of cancer (malignancies) have been reported in people receiving ORENCIA. It is not known if ORENCIA increases the chance of getting certain kinds of cancer.

Individuals should not receive ORENCIA with certain types of vaccines. ORENCIA may cause some vaccinations to be less effective.
Respiratory problems in people with COPD. Individuals may get certain respiratory problems more often if they receive ORENCIA and have COPD, including: worsened COPD, pneumonia, cough, or trouble breathing.

The more common side effects with ORENCIA in both adults and children are headache, upper respiratory tract infection, sore throat, and nausea. Other side effects in children may include diarrhea, cough, fever, and abdominal pain.

Please see accompanying Full Prescribing Information or visit www.ORENCIA.com or www.BMS.com.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information visit www.bms.com.

References:


3. J Kremer, R Westhovens, M Luggen, A Russell, R Aranda, J-C Becker, C Joshi, M Gandhi, MC Genovese. Long-term Efficacy and Safety of Abatacept Through 3 Years of Treatment in Rheumatoid Arthritis Patients in the AIM and ATTAIIN Trials. Oral presentation at: annual meeting of the American College of Rheumatology, Boston, Massachusetts, Thursday, November 8, 2:30 p.m. – 4:00 p.m.


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