Data from Phase II Exploratory Study Suggest That ORENCIA(R) (abatacept) May Delay Development of Rheumatoid Arthritis in Adults with Undifferentiated Inflammatory Arthritis

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Results Presented at the Annual Congress of the European League Against Rheumatism (EULAR)

PARIS--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced results from an exploratory Phase II study of 56 individuals that suggested that ORENCIA® (abatacept), a prescription drug for adults with moderate to severe rheumatoid arthritis (RA), may delay the development of RA in people with undifferentiated inflammatory arthritis (UA).

ORENCIA is not indicated for people with UA. In addition, further studies in larger patient populations of UA are required to validate these findings. The results were presented at the Annual Congress of the European League Against Rheumatism (EULAR), held in Paris, France, from June 11 to June 14.

In this small, randomized, double-blind, Phase II, multicenter, placebo-controlled, exploratory study, researchers investigated whether monotherapy with ORENCIA, administered for six months and then withdrawn, was more effective than placebo in delaying the development of RA in adult patients with UA who were positive for anti-cyclic citrullinated peptide (anti-CCP2) antibodies, a serum biomarker associated with increased risk of progression to erosive RA.

"Undifferentiated inflammatory arthritis is a common disease that, in some cases, may evolve into other rheumatic conditions, such as rheumatoid arthritis," said the study's lead investigator, Paul Emery, M.D., F.R.C.P., University of Leeds. "The results of this proof-of-concept study in a poor prognosis subset of UA patients support further study on the potential of ORENCIA to alter the course of disease towards RA."

"Bristol-Myers Squibb is committed to helping patients in their fight against rheumatoid arthritis," said Brian Daniels, M.D., rheumatologist and senior vice president, Global Development & Medical Affairs, Bristol-Myers Squibb. "We are excited by the potential of ORENCIA and will continue our efforts to help patients suffering from early forms of rheumatoid arthritis."

Study Design and Findings

In this study, 56 individuals with UA who were positive for anti-CCP2 antibodies were randomized to receive either monotherapy with ORENCIA® (abatacept) (n=28; dose approximating 10 mg/kg based on weight range) or placebo (n=28) for six months, after which treatment was discontinued.

The primary endpoint of this study was the proportion of patients who developed RA as measured by the American College of Rheumatology (ACR) criteria at Month 12, six months after treatment was ended.

At Year 1, 50 of the patients were evaluable and 12 of the 26 (46.2 percent) patients treated with ORENCIA developed RA, compared to 16 of the 24 (66.7 percent) placebo-treated patients (20.5 percent difference; 95 percent confidence interval +7.8 to -47.4).

The mean changes in Total Score, Erosion Score and Joint Space Narrowing Score from baseline to Year 1 were -0.02 units for ORENCIA versus 1.11 units for placebo, 0.02 units for ORENCIA versus 0.85 units for placebo and 0.00 units for ORENCIA versus 0.26 units for placebo, respectively. Further studies in larger patient populations of UA are required to validate these findings.

One patient in each of the ORENCIA and placebo groups discontinued due to an adverse event (3.6 percent for both arms). There were no discontinuations in either treatment group due to serious adverse events. There were 10 reports of infections (35.7 percent) in the arm treated with ORENCIA and 11 reports of infections (39.3 percent) in the placebo arm. There was one reported malignancy in the arm treated with ORENCIA (basal cell carcinoma, which investigators considered to be unrelated to the study drug).

About ORENCIA

ORENCIA is a prescription medicine that is used to treat adults with moderate to severe rheumatoid arthritis 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® (abatacept) also reduces signs and symptoms in children and adolescents six 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 Undifferentiated Inflammatory Arthritis**

Undifferentiated arthritis (UA) is a form of arthritis whose symptoms do not fulfill the classification criteria for a specific arthritic disease. Among those who seek a doctor's help for joint pain and stiffness, the most common diagnosis is UA. The prognosis of patients with UA may vary from self-limited to severe destructive RA. Forty to 50 percent of patients experience spontaneous remission of symptoms. About one-third of individuals with UA develop RA. Early treatment in UA patients may slow or prevent disease progression of joint damage into RA. ORENCIA is not indicated for the treatment of UA.

**About Rheumatoid Arthritis**

Rheumatoid arthritis 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 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), or a positive skin test for TB, recent close contact with someone who has had TB. If symptoms of TB occur (a dry cough, weight loss, fever, night sweats), they should call their doctor right away. Before starting treatment with ORENCIA® (abatacept), 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 use with 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 with other biologic medicines.

**Possible Side Effects of ORENCIA**

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® (abatacept). 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](http://www.ORENCIA.com) or [www.BMS.com](http://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](http://www.bms.com).

**Bristol-Myers Squibb Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the clinical development of the use of ORENCIA for people with UA will be successful. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2007, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

**References**


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English

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