Bristol-Myers Squibb to Present New Data on ORENCIA® (abatacept) at the European League Against Rheumatism (EULAR) 2012 Congress

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Results of a head-to-head study comparing two biologic drugs on a background of methotrexate for the treatment of moderate to severe rheumatoid arthritis to be presented

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that the company will present 18 abstracts on ORENCIA® (abatacept) at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology in Berlin, June 6-9. Among the data being presented will be results from the AMPLE study, a head-to-head phase 3 clinical trial comparing subcutaneous (SC) ORENCIA to HUMIRA® (adalimumab), both in combination with methotrexate. The combination of a biologic medication and methotrexate is the most commonly prescribed treatment approach in moderate to severe RA.

AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naive RA Subjects With Background Methotrexate) is a randomized, controlled study powered to compare the efficacy of ORENCIA SC versus HUMIRA on a background of methotrexate in adult, biologic naive patients with moderate to severe RA. AMPLE is an ongoing 2 year study, with primary analyses at 1 year. In addition to assessing the primary endpoint of non-inferiority between ORENCIA SC and HUMIRA as defined by the proportion of subjects achieving the American College of Rheumatology criteria of 20 percent improvement (ACR 20) after 12 months of treatment, the trial also evaluated the following secondary endpoints: frequency of injection site reactions, radiographic non-progression as assessed using the van der Heijde modified total Sharp score (mTSS) method, safety and retention. The study also evaluated additional efficacy measures including ACR 50, ACR 70 and disease activity scores (DAS).

“The data being presented highlight Bristol-Myers Squibb’s continued commitment to expanding our understanding of the efficacy and safety of ORENCIA, including important areas of study such as kinetics of response and radiographic non-progression,” said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. “AMPLE provides a direct comparison of ORENCIA SC and Humira, an important step to help address the lack of comparative studies among biologic medications for RA.”

In addition to the one-year results of AMPLE, other key data being presented at EULAR include:

- The first report of data on early response to abatacept plus methotrexate in patients not responding to methotrexate using power Doppler ultrasonograph.
- Results of a long-term comparison of ORENCIA® (abatacept) SC and its intravenous (IV) infusion formulation.
- New data on the efficacy and safety of the IV formulation of ORENCIA in patients with lupus nephritis.

Key presentations at the EULAR Annual European Congress of Rheumatology are shown below. The full set of abstracts can be accessed on the EULAR website.

Oral/Poster Presentations:

<table>
<thead>
<tr>
<th>Session Date, Time, Location</th>
<th>Presentation Title</th>
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<td>June 7, 2012, 10:30 AM, Hall 1.1</td>
<td>Abatacept SC Versus Adalimumab on Background Methotrexate in RA: One Year Results from the AMPLE Study</td>
<td>M. Schiff Denver, CO</td>
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About ORENCIA

In the United States, ORENCIA® (abatacept) subcutaneous (SC) and intravenous (IV) is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. ORENCIA may be used as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

ORENCIA IV is indicated for reducing signs and symptoms in pediatric patients 6 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. ORENCIA IV may be used as monotherapy or concomitantly with methotrexate (MTX). ORENCIA SC has not been studied in pediatric patients. ORENCIA should not be administered concomitantly with TNF antagonists.

ORENCIA is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy, such as anakinra.

ORENCIA is intended for use under the guidance of a physician or healthcare practitioner.

ORENCIA® (abatacept) IV was approved for patients initiating therapy with a biologic in 2005.

Important Safety Information

Concomitant Use with TNF antagonists: Concurrent therapy with ORENCIA and a biologic DMARD is not recommended. In controlled clinical trials, adult patients receiving concomitant intravenous ORENCIA and TNF antagonist therapy experienced more infections (63%) and severe infections (4.4%) compared to patients treated with only TNF antagonists (43% and 0.8%, respectively), without an important enhancement of efficacy.

Hypersensitivity: Less than 1% of adult patients treated with ORENCIA experienced hypersensitivity reactions, including some cases of anaphylaxis or anaphylactoid reactions. Other events potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in less than 0.9% of patients treated with ORENCIA and generally occurred within 24 hours of infusion. There was 1 case of a hypersensitivity reaction with ORENCIA in JIA clinical trials (0.5%; n =190). Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use in the event of a reaction.

Infections: Serious infections, including sepsis and pneumonia, have been reported in patients receiving ORENCIA. Some of these infections have been fatal. Many of the serious infections have occurred in patients on concomitant immunosuppressive therapy which in addition to their underlying disease, could further predispose them to infection. Caution should be exercised in patients with a history of infection or underlying conditions which may predispose them to infections. Treatment with ORENCIA should be discontinued if a patient develops a serious infection. Patients should be screened for tuberculosis, and viral hepatitis in accordance with published guidelines, and if positive, treated according to standard medical practice prior to therapy with ORENCIA.

Immunizations: Live vaccines should not be given concurrently with ORENCIA or within 3 months of its discontinuation as it may blunt the effectiveness of some immunizations. It is recommended that JIA patients be brought up to date with all immunizations in agreement with current immunization guidelines prior to initiating therapy with ORENCIA.

Use in Patients with Chronic Obstructive Pulmonary Disease (COPD): Adult COPD patients treated with ORENCIA® (abatacept) developed adverse events more frequently than those treated with placebo (97% vs 88%, respectively). Respiratory disorders occurred more frequently in patients treated with ORENCIA compared to those on placebo (43% vs 24%, respectively), including COPD exacerbations, cough, rhonchi, and dyspnea. A greater percentage of patients treated with ORENCIA developed a serious adverse event compared to those on placebo (27% vs 6%), including COPD exacerbation [3 of 37 patients (8%)] and pneumonia [1 of 37 patients (3%)]. Use of ORENCIA in patients with RA and COPD should be undertaken with caution, and such patients monitored for worsening of their respiratory status.

Blood Glucose Testing: ORENCIA for intravenous administration contains maltose, which may result in falsely elevated
blood glucose readings on the day of infusion when using blood glucose monitors with test strips utilizing glucose dehydrogenase pyrroloquinolinoquinone (GDH-PQQ). Consider using monitors and advising patients to use monitors that do not react with maltose, such as those based on glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase, or glucose hexokinase test methods. ORENCIA for subcutaneous administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

**Pregnant and Nursing Mothers:** ORENCIA should be used during pregnancy only if clearly needed. The risk for development of autoimmune diseases in humans exposed in utero to abatacept has not been determined. Nursing mothers should be informed of the risk/benefit of continued breast-feeding or discontinuation of the drug. A pregnancy registry has been established to monitor fetal outcomes. Healthcare professionals are encouraged to register pregnant patients exposed to ORENCIA by calling 1-877-311-8972.

**Most Serious Adverse Reactions:** Serious infections (3% ORENCIA vs 1.9% placebo) and malignancies (1.3% ORENCIA vs 1.1% placebo). In general, adverse events in pediatric and adolescent patients were similar in frequency and type to those seen in adult patients.

**Malignancies:** The overall frequency of malignancies was similar between adult patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in patients treated with ORENCIA (0.2%) than those on placebo (0%). A higher rate of lymphoma was seen compared to the general population; however, patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of ORENCIA® (abatacept) in the development of malignancies in humans is unknown.

**Most Frequent Adverse Events (≥10%):** Headache, upper respiratory tract infection, nasopharyngitis, and nausea were the most commonly reported adverse events in the adult RA clinical studies.

For US Full Prescribing Information, visit www.bms.com.

**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 joint function. The condition is more common in women than in men, who account for 75% 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 a monotherapy or concomitantly with DMARDs other than TNF antagonists. ORENCIA is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

**About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global biopharmaceutical company committed to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases.

For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

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English

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