New Investigational Data on ORENCIA® (abatacept) to be Presented at the American College of Rheumatology Annual Scientific Meeting

Release Date:
Thursday, November 3, 2011 9:00 am EDT

Terms:
R&D News

Dateline City:
NEW YORK

- Presentations on ORENCIA® (abatacept) provide further data on efficacy, safety, tolerability and retention
- Studies on abatacept in patients with lupus demonstrate ongoing commitment to ORENCIA and immune-related diseases

NEW YORK--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that 20 abstracts, including 18 which contain new investigational data from studies on ORENCIA® (abatacept) in patients with rheumatoid arthritis or lupus nephritis, will be presented at the American College of Rheumatology (ACR) Annual Scientific Meeting in Chicago November 5-9.

Abstracts from company-sponsored studies include new long-term data from the clinical trials that supported the recent U.S. Food and Drug Administration approval of subcutaneous (SC) ORENCIA for the reduction of signs and symptoms in adults with moderate to severe rheumatoid arthritis (RA).

The new data being presented on ORENCIA include:

- A first report of 24-month data from the ACQUIRE study, which evaluated the efficacy and safety of ORENCIA SC relative to the intravenous formulation in patients who were inadequate responders to methotrexate
- The first results from the 15-month extension of the ALLOW trial which evaluated the immunogenicity, safety and efficacy of ORENCIA SC following temporary withdrawal and re-introduction
- New results from a pooled analysis of 3,985 patients with up to 8 years of treatment, which describe the incidence of immunogenicity among patients using the intravenous formulation of ORENCIA
- The first results of a phase II study evaluating the efficacy and safety of abatacept over 12 months in patients with lupus nephritis

The company will also present safety data from up to 4.5 years of treatment with the subcutaneous formulation of ORENCIA in 1,879 patients with rheumatoid arthritis.

"The results presented at the American College of Rheumatology meeting reinforce Bristol-Myers Squibb’s commitment to expanding our understanding of the efficacy and safety of ORENCIA and continuing to address the unmet needs of adult patients with moderate to severe rheumatoid arthritis," said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. The full schedule of clinical presentations at the ACR Annual Scientific Meeting is as follows:

**Oral Presentations:**

<table>
<thead>
<tr>
<th>Session Date and Time</th>
<th>Presentation Title</th>
<th>Lead Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 8, 2011 2:30 PM – 2:45 PM</td>
<td>Efficacy and Safety of Abatacept Over 12 Months in Patients with Lupus Nephritis: Results From a Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase II/III Study</td>
<td>R. Furie Lake Success, NY</td>
</tr>
<tr>
<td>McCormick Place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Session: 2469</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convention Center: W 183 A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abatacept (ABA) for Lupus Nephritis: Alternative Outcome Measures Support Opposing Interpretations of Data from a Multicenter, Randomized, Double-blind, Placebo-controlled Phase II/III Study

D. Wolfsy
San Francisco, CA

November 8, 2011
3:45 PM – 4:00 PM
Oral Session: 2474
McCormick Place Convention Center: W 183 A

Poster Presentations:

<table>
<thead>
<tr>
<th>Session Date and Time</th>
<th>Presentation Title</th>
<th>Lead Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov. 6 9:00 AM - 6:00 PM</td>
<td>Subcutaneous (SC) Abatacept Versus Intravenous (IV) Abatacept in Patients with Rheumatoid Arthritis (RA): Long-term Data from the ACQUIRE (Abatacept Comparison of Sub[QU]cutaneous versus Intravenous in Inadequate Responders to Methotrexate) Trial</td>
<td>M. Genovese Palo Alto, CA</td>
</tr>
<tr>
<td>Nov. 6 9:00 AM - 6:00 PM</td>
<td>Clinical Efficacy and Pharmacokinetics of Subcutaneous Abatacept Received by Patients with Rheumatoid Arthritis in the Presence and Absence of an IV Loading Dose</td>
<td>P. Nash Brisbane, Australia</td>
</tr>
<tr>
<td>Nov. 6 9:00 AM - 6:00 PM</td>
<td>RAPID3, an index of only patient-reported measures, is similar to DAS28 and CDAI into guiding a “treat-to-target” strategy for rheumatoid arthritis in usual care</td>
<td>M. Bergman Ridley Park, PA</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Remission According to Different Composite Disease Activity Indices in Biologic-naïve Patients with Rheumatoid Arthritis Treated with Abatacept or Infliximab plus Methotrexate</td>
<td>J. Smolen Vienna, Austria</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Likelihood of achieving LDAS according to response at Months 1–6 in AGREE (TBC)</td>
<td>Y. Yazici New York, NY</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Pharmacokinetics of IV Abatacept in Systemic Lupus Erythematosus Patients with Active Proliferative Glomerulonephritis</td>
<td>M. Tagen Princeton, NJ</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Comparative Efficacy and Tolerability of Biologic Therapies in Early Rheumatoid Arthritis Utilizing a Bayesian Approach</td>
<td>Y. Yazici New York, NY</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Dose Escalation among Rheumatoid Arthritis Patients Treated with Infliximab or Abatacept: Comparison in Claims Data</td>
<td>T. Darkow Plainsboro, NJ</td>
</tr>
<tr>
<td>Nov. 7 9:00 AM - 6:00 PM</td>
<td>Comorbidity and Cost Burden of Patients Prior to Initiating Abatacept or Infliximab for Rheumatoid Arthritis</td>
<td>T. Darkow Plainsboro, NJ</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Subcutaneous Abatacept is Effective and Well Tolerated, With Low Immunogenicity following Temporary Withdrawal and Re-introduction in the Long Term Extension of the ALLOW Trial</td>
<td>J. Kaine Sarasota, FL</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Immunogenicity is Low and Transient with Intravenous Abatacept Therapy: Results from a Large Pooled Analysis of 3985 Patients with up to 8 Years’ Exposure</td>
<td>M. Weinblatt Boston, MA</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Safety of Subcutaneous Abatacept in 1879 Patients with Rheumatoid Arthritis and up to 4.5 Years Exposure: Focus on Events of Interest</td>
<td>R. Alten Berlin, Germany</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Maintained Disease Activity over 2 Years of Abatacept Treatment and Improved Disease Activity in Patients who Switch from MTX in Patients in the AGREE trial</td>
<td>R. Westhovens Leuven, Belgium</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Rate of Anti-Cyclic Citrullinated Peptide Antibody (CCP) and Rheumatoid Factor (RF) Serocconversion in Patients with Undifferentiated Arthritis (UA) or Rheumatoid Arthritis (RA) Treated with Abatacept</td>
<td>T. Huizinga Leiden, Netherlands</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Evaluation of Remission over 1 Year in Patients (pts) with Early Rheumatoid Arthritis (RA) Treated with Abatacept plus MTX, According to Simplified Disease Activity Index (SDAI)</td>
<td>J. Smolen Vienna, Austria</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Switching of Biologic Disease Modifying Anti-Rheumatic Drugs in patients with Rheumatoid Arthritis in a Real World Setting</td>
<td>B. Meissner Plainsboro, NJ</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>Treatment patterns in RA patients receiving abatacept or an anti-TNF agent as second-line biologic therapy</td>
<td>B. Meissner Plainsboro, NJ</td>
</tr>
<tr>
<td>Nov. 8 9:00 AM - 6:00 PM</td>
<td>RAPID3 is informative in patients with all rheumatic diseases to depict medical history information as quantitative data</td>
<td>I. Castrejón Madrid, Spain</td>
</tr>
</tbody>
</table>

About ORENCIA® (abatacept)
ORENCIA SC and IV are 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)
Rheumatoid arthritis (RA) is a systemic, chronic, autoimmune disease where the most commonly development of malignancies in humans is unknown. A higher rate of lymphoma was seen between adult patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in patients treated with ORENCIA compared to those on placebo (3% vs 0.2%) than those on placebo (0%).

ORENCIA IV is approved for patients initiating therapy with a biologic in 2005. Since launch, more than 71,000 patients in the U.S. have been prescribed ORENCIA IV. Clinical trials, ORENCIA IV has been shown to stop the progression of joint damage and has demonstrated efficacy and an established safety profile. Clinical trials for ORENCIA SC and IV have collected over 15,000 patient years of safety data.

**IMPORTANT SAFETY INFORMATION ABOUT ORENCIA**

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

**Concomitant Use with ORENCIA and Methotrexate (MTX):** ORENCIA 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 pyrroloquinolinequinone (GDH-PQQ). Consider using 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 (abatacept) 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. 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.

**Use in Patients with Chronic Obstructive Pulmonary Disease (COPD):** Adult COPD patients treated with ORENCIA 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 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 pyrroloquinolinequinone (GDH-PQQ). Consider using 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 (abatacept) 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).

**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 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. Click here for Full Prescribing Information, or visit www.ORENCIA.com or 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 (abatacept) is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

Please see accompanying Full Prescribing Information, or visit or www.bms.com.

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.

ORENCIA is a registered trademark of Bristol-Myers Squibb.

Language:
English

Contact:
Bristol-Myers Squibb Company
Media:
Ken Dominski, +1 609.252.5251
ken.dominski@bms.com
or
Investors:
John Elicker, +1 609.252.4611
john.elicker@bms.com

Ticker Slug:
Ticker: BMY
Exchange: NYSE