Bristol-Myers Squibb to Present New Investigational Data on Orencia® (abatacept) at the 2012 American College of Rheumatology Annual Scientific Meeting

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- One year results from AMPLE, first head-to-head Phase III clinical trial comparing subcutaneous (SC) Orencia to Humira® (adalimumab), both in combination with methotrexate, to be highlighted as a plenary podium presentation
- New patient reported outcomes data from the AMPLE trial also to be presented
- Orencia IV data will be presented in juvenile idiopathic arthritis and in mild relapsing granulomatosis with polyangiitis (Wegener’s)

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that new data from company-sponsored studies on Orencia SC in patients with rheumatoid arthritis (RA) and Orencia IV in juvenile idiopathic arthritis (JIA) will be presented at the American College of Rheumatology (ACR) Annual Scientific Meeting in Washington, D.C., November 10-14. Data from the company-sponsored studies will include new results from the AMPLE study examining changes in patient reported outcomes (PROs), including patient pain, patient global assessment and fatigue, and measures of remission. AMPLE (Abatacept Versus Adalimumab Comparison in Biologic-Naïve rheumatoid arthritis Subjects With Background Methotrexate) is a head-to-head Phase III non-inferiority clinical trial comparing subcutaneous (SC) Orencia to Humira® (adalimumab), each on a background of methotrexate. Additionally, investigator sponsored research, supported by BMS, studying Orencia IV in mild relapsing granulomatosis with polyangiitis (Wegener’s) will be presented.

Other new data being presented on Orencia include:
- A first report of pooled safety data in Orencia SC & IV formulations based on the exposure of more than 6,000 patients, which examines the incidence rates and events reported with long-term Orencia treatment.
- Long-term safety and efficacy of Orencia IV in pediatric patients 6 years of age and older with moderately to severely active polyarticular JIA, with results including up to seven years of follow-up.
- Analysis of the onset of treatment response and magnitude of efficacy improvement with Orencia SC over six months, with or without an intravenous Orencia loading dose.

“The one-year AMPLE results offer a more extensive and in-depth comparative analysis than previously reported between Orencia SC and Humira, and the patient reported outcomes continue to expand our understanding Orencia in moderate to severe RA,” said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. “The breadth of data at ACR is an example of our commitment to patients and to our continued research in RA and other diseases.”

Company-sponsored studies presented at the ACR Annual Scientific Meeting are shown below. Abstracts can be accessed on the ACR website at http://www.acrannualmeeting.org/.

**Key Orencia Data in Oral/Poster Presentations:**

<table>
<thead>
<tr>
<th>Session Date, Time, Location (all at Walter E. Washington Convention Center)</th>
<th>Presentation Title</th>
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<table>
<thead>
<tr>
<th>Date: Sunday, November 11</th>
<th>Time: 9:00 AM – 6:00 PM</th>
<th>Location: Poster Hall (Hall B)</th>
<th>Title: Subcutaneous Abatacept: Long-Term Data From the ACQUIRE Trial</th>
<th>M. Genovese Palo Alto, CA</th>
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<tbody>
<tr>
<td>Date: Sunday, November 11</td>
<td>Time: 9:00 AM – 6:00 PM</td>
<td>Location: Poster Hall (Hall B)</td>
<td>Title: Real-World Efficacy and Safety of Abatacept Treatment for Rheumatoid Arthritis: 12-Month Interim Analysis of the ACTION Study</td>
<td>H. Nüßlein Erlangen, Germany</td>
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<tr>
<td>Date: Sunday, November 11</td>
<td>Time: 4:30 PM – 6:00 PM</td>
<td>Location: Salon B</td>
<td>Title: Assessment of OMERACT Global Power Doppler Ultrasonography 44-Joint Scoring System and Reduced Joint Scoring Systems in Rheumatoid Arthritis Patients Treated with Abatacept Plus Background Methotrexate</td>
<td>M.A. D'Agostino Boulogne-Billancourt, France</td>
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<tr>
<td>Date: Sunday, November 11</td>
<td>Time: 4:30 PM – 6:00 PM</td>
<td>Location: Salon B</td>
<td>Title: The Relationship Between Power Doppler Ultrasonography Outcomes and Clinical Efficacy in Abatacept-Treated Patients with Rheumatoid Arthritis and Inadequate Response to Methotrexate</td>
<td>M.A. D'Agostino Boulogne-Billancourt, France</td>
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<tr>
<td>Date: Monday, November 12</td>
<td>Time: 9:00 AM – 6:00 PM</td>
<td>Location: Poster Hall (Hall B)</td>
<td>Title: Effects of SC Abatacept or Adalimumab on Remission and Associated Changes in Physical Function and Radiographic Outcomes: One Year Results from the AMPLE Trial</td>
<td>R. Fleischmann, Dallas, TX</td>
</tr>
<tr>
<td>Date: Monday, November 12</td>
<td>Time: 9:00 AM – 6:00 PM</td>
<td>Location: Poster Hall (Hall B)</td>
<td>Title: Changes in Patient Reported Outcomes in Response to Subcutaneous Abatacept or Adalimumab in Rheumatoid Arthritis: Results from the AMPLE Trial</td>
<td>R. Fleischmann, Dallas, TX</td>
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<tr>
<td>Date: Monday, November 12</td>
<td>Time: 4:30 PM – 6:00 PM</td>
<td>Location: 207 A</td>
<td>Title: Cumulative Long-Term Safety and Efficacy of Abatacept in Children with Juvenile Idiopathic Arthritis: Results up to 7 Years of Follow-up</td>
<td>D. Lovell Cincinnati, OH</td>
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<tr>
<td>Date: Monday, November 12</td>
<td>Time: 4:30 PM – 6:00 PM</td>
<td>Location: Hall E</td>
<td>Title: Prolonged Exposure to Subcutaneous and Intravenous Abatacept in Patients with Rheumatoid Arthritis Does Not Affect Rates of Infection, Malignancy and Autoimmune Events: Results From Pooled Clinical Trial Data</td>
<td>M. Genovese Palo Alto, CA</td>
</tr>
<tr>
<td>Date: Tuesday, November 13</td>
<td>Time: 11:00 AM – 12:30 PM</td>
<td>Location: Hall E</td>
<td>Title: Subcutaneous Abatacept versus Adalimumab in the Treatment of Rheumatoid Arthritis: 1 Year Results from the AMPLE Trial</td>
<td>M. Weinblatt Boston, MA</td>
</tr>
<tr>
<td>Date: Tuesday, November 13</td>
<td>Time: 4:30 PM – 6:00 PM</td>
<td>Location: Hall E</td>
<td>Title: Weekly Subcutaneous Abatacept Confers Comparable Onset of Treatment Response and Magnitude of Efficacy Improvement Over 6 Months When Administered with or without an Intravenous Abatacept Loading Dose</td>
<td>M. Schiff Denver, CO</td>
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**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) 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.

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 serious 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® (abatacept) 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 is 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 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 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® (abatacept) 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 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 http://packageinserts.bms.com/pi/pi_orencia.pdf.

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.

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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*Exchange: NYSE*