Bristol-Myers Squibb to Present New Remission Data on ORENCIA® (abatacept) and Clazakizumab at The European League Against Rheumatism (EULAR) 2014 Annual Meeting

Release Date: Wednesday, May 21, 2014 8:00 am EDT

Terms:

Dateline City: PRINCETON, N.J.

- First presentation of results from the Phase IIIb AVERT study highlighting induction of remission with Orencia in patients with highly-active early rheumatoid arthritis (RA)
- New data from the two-year head-to-head AMPLE trial, evaluating Orencia vs. Humira® (adalimumab) in RA, also to be presented
- Presentation of 24-week efficacy, safety and MRI data from a Phase IIb trial of clazakizumab, an investigational selective IL-6 cytokine inhibitor for RA

PRINCETON, N.J.-- (BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that 20 abstracts for Orencia® (abatacept), and clazakizumab have been accepted for presentation at the 2014 annual meeting of the European League Against Rheumatism (EULAR), to be held June 11-14 in Paris, France. The extensive data being presented underscores the Company’s commitment to develop innovative treatments for patients suffering from rheumatoid arthritis (RA) and other immune-mediated diseases, including its pioneering T-cell co-stimulation modulator, Orencia, and clazakizumab, an investigational selective IL-6 cytokine inhibitor.

“Leveraging our heritage and expertise in immunoscience, Bristol-Myers Squibb remains focused on changing the course of immune-mediated diseases like RA,” said Michael Giordano, senior vice president, Head of Development, Oncology and Immunoscience, Bristol-Myers Squibb. “The clinical results and real-world data we will present at the EULAR annual meeting reflect our commitment to develop innovative therapies to improve the health of patients suffering from RA.”


<table>
<thead>
<tr>
<th>Title</th>
<th>Date/Time</th>
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<tbody>
<tr>
<td>Induction of Clinical Remission Followed by Drug-free Withdrawal with Abatacept Combination and Monotherapy in Early RA: Results from the AVERT Study Over 18 Months</td>
<td>June 12, 2014 at 10:30 a.m. CET</td>
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<td>MRI Results from the AVERT Study: A Randomized, Active-Controlled Trial to Evaluate Induction of Remission and Maintenance of Drug-Free Remission Using Abatacept in Combination with Methotrexate or as Monotherapy in Patients with Early RA</td>
<td>June 12, 2014 at 11:10 a.m. CET</td>
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<td>Modulation of the ACPA Fine Specificity in Patients with RA Treated with Either Abatacept or Adalimumab in the AMPLE Study</td>
<td>June 13, 2014 at 11:45 a.m. CET</td>
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<tr>
<td>Clinical Responses By Baseline RA Disease Duration in the AMPLE (Abatacept versus Adalimumab Comparison in Biologic-Naive RA Patients with Background Methotrexate) Trial: 2-Year Results</td>
<td>June 13, 2014 at 11:45 a.m. CET</td>
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Comparison of Abatacept and Other Biologic DMARDS for the Treatment of Rheumatoid Arthritis Patients: A Systematic Literature Review and Network Meta-Analysis

Correlation of Clinical Response with Patient-Reported Outcomes in the AMPLE (Abatacept versus Adalimumab Comparison in Biologic-Naïve RA Patients with Background Methotrexate) Trial: 2-Year Results

Association of Radiographic Outcomes with Low Disease Activity and Remission and Sustainability of Response with Subcutaneous Abatacept or Adalimumab: 2-Year Results from the AMPLE Trial

Two-Year Retention and Effectiveness of Abatacept in Real-Life Setting: Results from the ACTION Study

Two-Year Retention and Effectiveness of IV Abatacept Monotherapy and Combination in PTS With RA Previously Treated With at Least One Biologic Agent in a Real-Life Setting: Subgroup Analysis From the ACTION Study

Decreased Use of Glucocorticoids in PTS With RA Who Initiated IV Abatacept and Previously Failed At Least One Biologic Agent: Results From the 2-Year Action Study

Gene Expression in Whole Blood Predicts the Abatacept-Methotrexate Combination Responsiveness in Rheumatoid Arthritis: Preliminary Results From the Power Doppler Ultrasoundography Appraise Study

CLAZAKIZUMAB

A Phase IIB Study of the Efficacy and Safety of Subcutaneous Clazakizumab (Anti-IL-6 Monoclonal Antibody) With or Without Methotrexate in Adults With Moderate-to-Severe Active Rheumatoid Arthritis and an Inadequate Response to Methotrexate

X-Ray and MRI Results From a Phase IIB Study of Subcutaneous Anti-interleukin-6 Monoclonal Antibody Clazakizumab With or Without MTX in Adults with Moderate-to-Severe Active Rheumatoid Arthritis and an Inadequate Response to Conventional DMARDS Including Methotrexate

Health Economics & Outcomes Research

Differences (or Variations) in Physical Function in RA By Disease Activity Levels Defined by DAS, CDAI, and SDAI in Clinical Practice

Development and Validation of a Prognostic Clinical Model for Rapid Radiographic Progression in Patients with RA

The Role of C-Reactive Protein or Erythrocyte Sedimentation rate in Predicting Cardiovascular Outcomes in Rheumatoid Arthritis of Data From US Managed Care Organization

Quality of Life and Economic Benefits of Remission/Low Disease Activity in Patients with Rheumatoid Arthritis in Clinical Practice Setting

Performance of the Framingham Cardiovascular Risk Prediction Model With or Without CRP in RA Patients: Analysis of UK Clinical Practice Research Data

Performance of the Framingham Cardiovascular Risk Prediction Model With and Without C-Reactive Protein or Erythrocyte Sedimentation Rate in RA: Analysis of US Electronic Medical Records Database

DISEASE-STATE PRESENTATION
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 ORENCIA® (abatacept)

ORENCIA SC and 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.

Indication/Usage and Important Safety Information for ORENCIA® (abatacept)

Indication/Usage

Adult Rheumatoid Arthritis (RA): ORENCIA® (abatacept) is a prescription medicine that reduces signs and symptoms in 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 your bones and joints and may help your ability to perform daily activities. In adults, ORENCIA may be used alone or with other RA treatments other than tumor necrosis factor (TNF) antagonists.

Juvenile Idiopathic Arthritis (JIA): 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). ORENCIA may be used alone or with methotrexate (MTX).

Important Safety Information About ORENCIA® (abatacept)

Inform your healthcare provider of the following, before you receive treatment with ORENCIA:

Infections: If you have any kind of infection, even if it is small (such as an open cut or sore), an infection that is in your whole body (such as the flu), an infection that will not go away, or a history of infections that keep coming back. ORENCIA may make your immune system less able to fight infections, so you may be more likely to get infections or any infection you have may get worse.

Tuberculosis: If you have had tuberculosis (TB), a positive skin test for TB, or if you recently have been in close contact with someone who has had TB. If you get any of the symptoms of TB (a dry cough that does not go away, weight loss, fever, night sweats), call your healthcare provider right away. Before you start ORENCIA, your healthcare provider may examine you for TB or perform a skin test.

If you have or have had Viral Hepatitis. Before you use ORENCIA, your healthcare provider may examine you for hepatitis.

If you have a history of Chronic Obstructive Pulmonary (lung) Disease (COPD).

If you are scheduled to have Surgery.

Allergies to the Ingredients of ORENCIA® (abatacept): The ingredients of intravenous (IV) ORENCIA are: abatacept, maltose, monobasic sodium phosphate, and sodium chloride for administration. The ingredients of subcutaneous (SC) ORENCIA are: abatacept, sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, and water for injection.

Vaccinations: If you have recently received a vaccination or are scheduled for any vaccination. If you are receiving ORENCIA, and for 3 months after you stop receiving ORENCIA, you should not take live vaccines.

Diabetes: If you have diabetes and use a blood glucose monitor to check your sugar levels. The Infusion of ORENCIA contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day you receive your infusion. Your healthcare provider may tell you to use a different way to monitor your blood sugar levels. ORENCIA for SC injection does not contain maltose; therefore, you do not need to change the way you monitor your blood sugar if you are taking ORENCIA subcutaneously.

Pregnancy: If you are pregnant, planning to become pregnant, or are thinking about becoming pregnant. It is not known if ORENCIA can harm your unborn baby.
**Breastfeeding:** You will need to decide to either breast-feed or receive treatment with ORENCIA, but not both.

If you **Take Any Other Kinds of Medicine**, including prescription and nonprescription medicines, vitamins, and herbal supplements.

If you are **Taking Other Biologic Medicines to Treat RA** such as: Enbrel®, (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra), Rituxan® (rituximab), Simponi® (golimumab), Cimzia® (certolizumab pegol), Actemra® (tocilizumab). You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines.

**Possible Side Effects of ORENCIA® (abatacept)**

ORENCIA can cause serious side effects including:

- **Serious infections.** ORENCIA can make you more likely to get infections or make the infection that you have get worse. Some patients have died from these infections. Call your healthcare provider immediately if you 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.** Allergic reactions can happen on the day of treatment or the day after receiving ORENCIA. Tell your healthcare provider if you get any sign of an allergic reaction to ORENCIA such as: rash; hives; swelling of your mouth, face, or lips; difficulty breathing; or an allergic reaction that affects your voice or makes it hard to breath.

- **Hepatitis B infection.** If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use ORENCIA. Your healthcare provider may do a blood test before you start or while using ORENCIA.

- **Vaccinations.** You should not receive ORENCIA® (abatacept) with certain types of vaccines. ORENCIA may cause some vaccinations to be less effective.

- **Respiratory problems in patients with COPD.** You may get certain respiratory problems more often if you receive ORENCIA and have COPD, including: worsened COPD, pneumonia, cough, or trouble breathing.

- **Cancer (malignancies).** Certain kinds of cancer have been reported in patients receiving ORENCIA. It is not known if ORENCIA increases your chance of getting certain kinds of cancer.

**Common side effects** with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea. Other side effects in children and adolescents may include diarrhea, cough, fever, and abdominal pain.

**Note concerning use in children under 18 years of age:** ORENCIA for SC injection has not been studied in children under 18 years of age, therefore it is not known if ORENCIA for SC injection is safe and effective in children under 18 years of age.

**Please read the Patient Information in the Full US Prescribing Information.**

**About Clazakizumab**

Clazakizumab is an investigational selective IL-6 cytokine inhibitor, under investigation for the treatment of RA. Bristol-Myers Squibb has exclusive worldwide rights to develop and commercialize clazakizumab for all indications outside of cancer under a collaboration agreement with its discoverer, Alder Biopharmaceuticals. Clazakizumab is the second biologic treatment for RA being developed by Bristol-Myers Squibb, demonstrating the company’s long-standing commitment to immunoscience.

**About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

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

ORENCIA® (abatacept) is a registered trademark of Bristol-Myers Squibb Company.

**About Bristol-Myers Squibb Immunoscience**

The immune system is the body’s natural defense against disease. These processes come into play in almost every human disease. That is why Bristol-Myers Squibb is focused on exploring ways to harness the body’s own immune system to treat immune-related diseases with high unmet medical needs, including RA – a chronic, systemic, inflammatory autoimmune disorder that affects the joints.

**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 the research, development and commercialization of pharmaceutical products. 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. 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, 2013 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.
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