Bristol-Myers Squibb to Showcase New Data Spanning Rheumatoid Arthritis and Other Autoimmune Diseases at 2016 American College of Rheumatology and Association of Rheumatology Health Professionals Annual Meeting

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Analyses explore ORENCIA ® (abatacept) treatment and disease burden among patients with poor prognostic factors for rapidly progressive rheumatoid arthritis (RA)

New abatacept data from Phase 3 psoriatic arthritis and juvenile idiopathic arthritis studies

Pipeline Phase 2 and 3 data highlight Bristol-Myers Squibb’s commitment to researching novel immune pathways

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that 23 abstracts related to ORENCIA ® (abatacept) and the company’s immunoscience pipeline will be presented at the 2016 annual meeting of the American College of Rheumatology (ACR) and the Association of Rheumatology Health Professionals (ARHP) to be held November 11-16 in Washington, D.C. These data highlight Bristol-Myers Squibb’s significant capabilities in immunoscience research and its commitment to meeting the unmet needs of patients living with autoimmune diseases.

“As a leader in immunoscience, Bristol-Myers Squibb is advancing our work in rheumatoid arthritis and fostering therapeutic advancements for related autoimmune diseases,” said Brian J. Gavin, Vice President, ORENCIA Development Lead, Bristol-Myers Squibb. “The broad range of data being shared at ACR/ARHP this year reflects our focus on improving patient care through immuno-modulation, exploring investigational treatment pathways and defining the role that biomarkers may play in informing therapeutic decisions in rheumatologic disease.”

The full listing of abstracts Bristol-Myers Squibb will present at the 2016 ACR/ARHP annual meeting follows. Multiple abstracts focus on the impact of anti-citrullinated protein antibody positivity, also known as ACPA positivity, among patients with RA. Bristol-Myers Squibb’s ACPA-related research is focused on furthering the understanding of ACPA as a key prognostic factor related to rapidly progressive RA. In addition, data from recently completed abatacept Phase 3 trials in psoriatic arthritis (PsA) and polyarticular juvenile idiopathic arthritis (pJIA) will be presented. Bristol-Myers Squibb will also present late-breaking data exploring preclinical models of systemic lupus erythematosus and inflammatory bowel disease on November 13th at 9:00 a.m. - 11:00 a.m. EST. Complete abstracts can be accessed online at: http://acrannualmeeting.org/abstracts/.

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<td>BMS-986165 is a Highly Potent and Selective Allosteric Inhibitor of Tyk2, Blocks IL-12, IL-23 and Type I Interferon Signaling and Provides for Robust Efficacy in Preclinical Models of Systemic Lupus Erythematosus and Inflammatory Bowel Disease</td>
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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, and swelling in the joints. RA causes decreased range of motion and function in the joints. The condition is three times more common in women than in men.

**U.S. Indications/Usage and Important Safety Information for ORENCIA® (abatacept)**

**Indication and Usage**

**Adult Rheumatoid Arthritis (RA):** ORENCIA® (abatacept) 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 RA. ORENCIA may be used as monotherapy or concomitantly with disease-modifying, anti-rheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

**Juvenile Idiopathic Arthritis (JIA):** ORENCIA® (abatacept) is indicated for reducing signs and symptoms in pediatric patients aged 6 years and older with moderately to severely active polyarticular JIA. ORENCIA may be used as monotherapy or concomitantly with methotrexate (MTX).

**Important Limitations of Use:** ORENCIA should not be administered concomitantly with TNF antagonists, and is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

**Important Safety Information for ORENCIA® (abatacept)**

**Concomitant Use with TNF Antagonists:** Concurrent therapy with ORENCIA and a TNF antagonist 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:** Anaphylaxis or anaphylactoid reactions can occur during or after an infusion and can be life-threatening. There were 2 cases (<0.1%; n=2688) of anaphylaxis or anaphylactoid reactions in clinical trials with adult RA patients treated with intravenous ORENCIA. Other reactions potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in <0.9% of patients. There was one case of a hypersensitivity reaction with ORENCIA in JIA clinical trials (0.5%; n=190). In postmarketing experience, a case of fatal anaphylaxis following the first infusion of ORENCIA was reported. Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use. If an anaphylactic or other serious allergic reaction occurs, administration of ORENCIA should be stopped immediately and permanently discontinued, with appropriate therapy instituted.

**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. The efficacy of vaccination in patients receiving ORENCIA is not known. ORENCIA 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 exacerbation, cough, rhinorhea, 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 pyrroloquinoline quinone (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 (SC) administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

**Pregnancy:** There are no adequate and well-controlled studies of ORENCIA use in pregnant women and the data with ORENCIA use in pregnant women are insufficient to inform on drug-associated risk. A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to ORENCIA during pregnancy. Healthcare professionals are encouraged to register patients by calling 1-877-311-8972.

**Lactation:** There is no information regarding the presence of abatacept in human milk, the effects on the breastfed infant, or the effects on milk production. However, abatacept was present in the milk of lactating rats dosed with abatacept.

**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. Other events reported in ≥5% of JIA patients were diarrhea, cough, pyrexia, and abdominal pain. In general, the adverse events in pediatric patients were similar in frequency and type to those seen in adult patients.

**Note Concerning SC ORENCIA:** The safety and efficacy of SC ORENCIA have not been studied in patients under 18 years of age.


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

**About Bristol-Myers Squibb Immunoscience**

With a robust pipeline of immunomodulatory therapies, Bristol-Myers Squibb is committed to the discovery and development of transformational medicines that could lead to long-term remission in patients with autoimmune diseases. As we discover more about the immune system in such diseases with substantial unmet medical needs, the potential for developing novel therapies that target specific pathways in the immune system continues to drive our research efforts.

**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 us at [BMS.com](http://www.bms.com) or follow us on [LinkedIn](http://www.linkedin.com), [Twitter](http://www.twitter.com), [YouTube](http://www.youtube.com) and [Facebook](http://www.facebook.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 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 discussed in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2015 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**


English

**Contact:**
Bristol-Myers Squibb Company
Media:
Erin McMaster, 609-955-2253
erin.mcmaster@bms.com
or
Investors:
Bill Szablewski, 609-252-5894
william.szablewski@bms.com

**Ticker Slug:**
*Ticker: BMY*
*Exchange: NYSE*

Organization,Twitter,Link to BMS News Twitter page:
#BMS announces 23 presentations in #RA and autoimmune diseases at the #ACR16 annual meeting:
https://twitter.com/bmsnews