Bristol-Myers Squibb to Showcase Company’s Progress in Researching Personalized Medicine for the Potential Treatment of Autoimmune Diseases at 2017 American College of Rheumatology and Association of Rheumatology Health Professionals Annual Meeting

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ORENcia® (abatacept) rheumatoid arthritis data examine potential therapeutic benefit and cost effectiveness in the treatment of patients with highly active, progressive disease

Juvenile idiopathic arthritis study evaluates ORENCIA efficacy at two years in patients 2-17 years old

New pipeline data reflect Company’s long-term commitment to addressing unmet needs in autoimmune diseases

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today confirmed that 34 abstracts related to ORENCIA® (abatacept) and the Company's immunoscience pipeline will be presented at the 2017 American College of Rheumatology and Association of Rheumatology Health Professionals Annual Meeting, November 3-8, 2017, in San Diego. Building on its heritage of discovering and developing medicines designed to help modulate the body's immune response to treat autoimmune disease and cancer, the Company will share clinical and real-world ORENCIA data across rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA) and active psoriatic arthritis, as well as pre-clinical and first-in-human data from BMS-986195, an investigational Bruton's Tyrosine Kinase (BTK) inhibitor.1,2

The Bristol-Myers Squibb data being presented will include new insights about how ORENCIA impacts outcomes and treatment costs in patients who exhibit key biomarkers of highly active, progressive RA, such as anti-citrullinated protein antibodies (ACPA), as well as analyses evaluating the link between these biomarkers and certain advanced disease hallmarks such as structural damage progression.3-8 Treatment retention and safety data in the real-world setting to be presented adds to the growing body of evidence on ORENCIA,9,10 a selective T-cell co-stimulation modulator.

"Bristol-Myers Squibb's research continues to advance the understanding of the relationship between biomarkers such as ACPA and disease prognosis. These biomarkers play an important role in both identification of patients facing highly active, progressive disease, who traditionally have had poor prognoses, and their treatment plans," said Brian Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb. “The ORENCIA data we are presenting at the ACR/ARHP Annual Meeting are reflective of our commitment to advancing the science and addressing unmet needs in autoimmune diseases with the ultimate goal of enabling personalized ‘right treatment for the right patient’ approaches.”

Beyond RA in adults, Bristol-Myers Squibb data evaluating the efficacy and safety of ORENCIA in patients aged 2-17 with JIA followed for up to two years will be presented,11 as will pre-clinical and first-in-human data from BMS-986195, an investigational BTK inhibitor.1,2 Bruton's tyrosine kinase (BTK) is an enzyme found inside certain immune cells that plays a fundamental role in the immune response to antigens, which are proteins recognized as foreign materials in the body.12,13

The full listing of abstracts sponsored by Bristol-Myers Squibb at the 2017 ACR/ARHP Annual Meeting follows. Complete abstracts can be accessed online here.
### Patient Benefit Analyses

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<td>Comparative Risk of Biologic Therapies in Patients with Rheumatoid Arthritis Undergoing Elective Arthroplasty</td>
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<td>2868</td>
<td>Pharmacodynamic Analysis of Whole Blood Gene Expression Over 2 Years in a Phase IIIb Head-to-Head Trial of Abatacept and Adalimumab in Patients With RA</td>
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<td>2855</td>
<td>SC Aba in Pts Aged 2–17 Yrs With pJIA and inadequate Response to Biologic or Non-biologic Disease-Modifying Antirheumatic Drugs: Pharmacokinetics, Effectiveness, Safety and Immunogenicity Over 2 Yrs</td>
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<td>Do Certain DMARDs Increase Risk of New-Onset Type 2 Diabetes in RA Patients? A Disease Risk Score Analysis Using Administrative Databases</td>
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<td>Abatacept Shows Better Sustainability Than TNF Inhibitors When Used Following Initial Biologic DMARD Failure in the Treatment of RA: 8 Years of Real-World Observations from the Rhumadata Clinical Database and Registry</td>
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<td>1468</td>
<td>Abatacept Retention Rates, Overall and by Participating Country, and Prognostic Factors of Retention in Patients With RA: 2-Year Results From a Real-World Observational Study</td>
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### Cost Analyses

**Abstract 1465:** Cost per Response for Abatacept Versus Adalimumab in Patients With Seropositive, Erosive, Early Rheumatoid Arthritis in the US, Germany, Spain and Canada

**Poster**

**Abstract 413:** Economic Burden Associated With Anti-cyclic Citrullinated Peptide Antibody Positivity in Pts Newly Diagnosed with RA

**Poster**

### Immunoscience Pipeline

**Abstract 514:** BMS-986195, a Novel, Rapidly Acting, Covalent Inhibitor of Bruton’s Tyrosine Kinase: Safety, Pharmacokinetic and Pharmacodynamic Profiles in Healthy Participants

**Poster**

**Abstract 503:** BMS-986195 Is a Highly Selective and Rapidly Acting Covalent Inhibitor of Bruton’s Tyrosine Kinase with Robust Efficacy at Low Doses in Preclinical Models of RA and Lupus Nephritis

**Poster**

### 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, and swelling. 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**

Orencia® 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® is indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia® may be used as monotherapy or concomitantly with methotrexate (MTX).

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.

**U.S. Indications/Usage and Important Safety Information forORENCIA® (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 antirheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

**Juvenile Idiopathic Arthritis (JIA):** Orencia® (abatacept) is indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular JIA. Orencia® may be used as monotherapy or concomitantly with methotrexate (MTX).

**Adult Psoriatic Arthritis (PsA):** Orencia® (abatacept) is indicated for the treatment of adult patients with active PsA.

**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 RA 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, including COPD exacerbations, cough, rhonchi, and dyspnea. In adult RA studies, 97% of COPD patients treated with Orencia® developed adverse reactions versus 88% treated with placebo and respiratory disorders occurred more frequently in patients treated with Orencia® compared to those on placebo (43% vs 24%, respectively), including COPD exacerbation, cough, rhonchi, and dyspnea. A greater percentage of adult RA 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 pyroloquinoline 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 RA patients treated with ORENCIA or placebo. However, more cases of lung cancer were observed in RA 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 JIA and adult PsA patients were similar in frequency and type to those seen in adult RA patients.

**Note concerning ORENCIA administration options:** Intravenous dosing has not been studied in patients younger than 6 years of age. The safety and efficacy of ORENCIA ClickJect™ Autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

Please click here to see the Full Prescribing Information.

**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. We continue to pioneer novel approaches to optimize the body’s immune response with the hope of delivering life changing medicine for patients with auto-immune diseases like lupus, rheumatoid arthritis and inflammatory bowel disease, where substantial unmet medical need exists. As we discover more about the immune system in such diseases 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 or follow us on LinkedIn, Twitter, YouTube and Facebook.

**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, 2016 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**


Language: English

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