Bristol-Myers Squibb Announces New Rheumatoid Arthritis Research and Real-World Data at the Annual European Congress of Rheumatology (EULAR 2016)

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Dateline City:
PRINCETON, N.J.

Presentation of the first U.S. observational study exploring the impact of biomarkers on treatment response for Orencia and TNF-inhibitors in moderate to severe rheumatoid arthritis

In this study, patients who tested positive via a common blood test for certain biomarkers of poor prognosis (anti-CCP or RF) were more likely to have a greater response with Orencia treatment than patients testing negative for the biomarkers

Other data being presented: More than 20 abstracts, including new pediatric study findings demonstrating equivalent efficacy and safety of subcutaneous Orencia to intravenous Orencia in pediatric juvenile idiopathic arthritis patients and the first data disclosure of Phase 1 data showing investigational BTK inhibitor, BMS-986142, for the treatment of rheumatoid arthritis and other inflammatory disease was well tolerated

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that it will present new data – offering insights into the field of rheumatoid arthritis (RA) – at the Annual European Congress of Rheumatology (EULAR 2016), to be held June 8-11, in London, UK.

Among the studies that Bristol-Myers Squibb will present are findings from the first U.S. observational study exploring patients’ response to treatment based on their baseline status for two biomarkers of poor prognosis, anti-cyclic citrullinated peptide (anti-CCP, also known as ACPA) and rheumatoid factor (RF). Both anti-CCP and RF are biomarkers of poor prognosis which may be associated with more severe disease progression and joint damage. This new study and its results will be featured in an Annual European Congress of Rheumatology (EULAR 2016) press release and in an oral presentation on Thursday, June 9, 10:50 CET.

The study analyzed data from the Corrona, LLC RA registry, the largest RA cohort prospectively followed in North America. The analysis included patients with RA who had been tested for both anti-CCP and RF, and received Orencia, a T cell co-stimulation blocker (n=566), or another class of RA biologic medicines, TNF-inhibitors (n=1715), between June 2002 and January 2015. The primary outcome measured in the analysis was mean change from baseline in Clinical Disease Activity Index (CDAI) at six months and secondary outcomes were achievement of low disease activity (LDA) at six months (LDA; CDAI ≤2.8 among those with low, moderate or high disease activity at baseline). Response rates for Orencia and TNF-inhibitors were evaluated based on serologic status: double positive (anti-CCP+/RF+); single positive (anti-CCP+/RF- or anti-CCP-/RF+); and double negative (anti-CCP-/RF-).

Topline results from the real-world data analysis showed that in patients who initiated Orencia, double positive status was associated with a significantly greater response compared with double negative status on all outcomes (CDAI−8.9 vs. −4.5, p=0.002; LDA 43% vs. 26%, p=0.002; remission 15% vs. 5%, p=0.001). In addition, single positive status was associated
with a greater likelihood of remission as compared with double negative status for those administered Orencia (12% vs. 5%, p=0.018). The study did not show significant differences in responses between anti-CCP/RF status in those administered TNF-inhibitors (double positive vs. double negative: CDAI –7.5 vs. –6.8, p=0.46; LDA 39% vs. 35%, p=0.20; remission 16% vs. 14%, p=0.38).

“The Corrona RA registry offers an unrivaled source of real-world observational data collected from U.S. patients with RA,” said Leslie Harrold, M.D., M.P.H., the study’s Principal Investigator and an Associate Professor of Medicine and Orthopedics and Physical Rehabilitation at the University of Massachusetts Medical School as well as Senior Medical Director of Pharmacoeconomics and Outcomes research at Corrona. “We believe our findings provide new insights on RA for the rheumatology community.”

The Corrona RA registry is a real-world observational study that has collected data from 662 participating rheumatologists in 168 rheumatology practices across 40 states in the U.S. It currently includes data from more than 40,000 patients with RA.

“As a leader in the field of immunoscience, Bristol-Myers Squibb is dedicated to the research of disease biomarkers and finding transformative ways that may help reduce the impact of autoimmune diseases like RA,” said Douglas Manion, M.D., Head of Specialty Development, Bristol-Myers Squibb. “The real-world data from the Corrona RA registry study showed patients who are seropositive for anti-CCP or RF, and particularly those who are double seropositive, were more likely to have incremental improvements in response to Orencia than if they were negative for these biomarkers as compared to those who initiated TNF-inhibitors. In addition, there was differential response to Orencia but not with TNF-inhibitors in patients who were CCP+ vs. CCP-. These findings and scientific insights underscore our decade-long commitment to ongoing Orencia research.”

Other key data Bristol-Myers Squibb is presenting at the Annual European Congress of Rheumatology (EULAR 2016) includes:

- Phase 3 data from the AVERT (Assessing Very Early Rheumatoid Arthritis Treatment) study, which evaluated the efficacy and safety of re-treating patients with early, active RA (tested positive for anti-CCP) with Orencia plus methotrexate after a period of treatment withdrawal. The full analysis of the data will be featured in a poster presentation on Saturday, June 11, 10:20 CET.
- A Phase 3 juvenile idiopathic arthritis (pJIA) study demonstrating subcutaneous (SC) Orencia has equivalent efficacy and comparable safety to intravenous (IV) Orencia for pJIA patients. SC Orencia showed efficacy after four months with greater than 80% of patients achieving an ACR30 response with few clinically relevant adverse events. The data will be featured in an oral presentation on Friday, June 10, 10:20 CET.
- The first data disclosure for Bristol-Myers Squibb’s investigational Bruton’s Tyrosine Kinase (BTK) inhibitor, BMS-986142, targeted for RA and other inflammatory diseases. Researchers will report on Phase 1 data which showed that BMS-986142 was well tolerated, warranting further development of the agent. The data will be featured in a poster presentation on Thursday, June 9, 11:45 CET.

The full listing of abstracts Bristol-Myers Squibb will present at the Annual European Congress of Rheumatology (EULAR 2016) follows. Complete abstracts can be accessed online via the Annual European Congress of Rheumatology (EULAR 2016) program planner at https://b-com.mci-group.com/AbstractList/EULAR2016.aspx.

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<td>SAT0153/AVERT</td>
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**BTK Inhibitor**
### 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 the Corrona RA Registry

The Corrona RA registry is the largest RA cohort prospectively followed in North America and consists of data collected from both physicians and patients at the time of a clinical encounter. The Corrona RA registry offers insights from more than 40,000 RA patients and 130,000+ patient-years of longitudinal follow-up between June 2002 and January 2015.

### About Orencia

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.

### 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 undergoing 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, 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 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.

Please see Full Prescribing Information at http://packageinserts.bms.com/pi/pi_orencia.pdf.

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 may lead to long-term remission in patients suffering from immune-mediated disease. As we learn more about the immune system in diseases with substantial unmet needs, the potential for new therapies that modulate 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, 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.

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