Bristol-Myers Squibb Showcases Rheumatoid Arthritis and Immunoscience Commitment with Depth of Research at 2016 American College of Rheumatology and Association of Rheumatology Health Professionals Annual Meeting

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Presentation of real-world data demonstrating that biomarkers of poor prognosis may help identify rheumatoid arthritis (RA) patient populations at risk for rapidly progressing disease

New ORENCIA® (abatacept) data in RA and related autoimmune diseases featured in multiple presentations

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today unveiled rheumatoid arthritis (RA) and autoimmune disease data being presented at the 2016 Annual Meeting of the American College of Rheumatology (ACR) and the Association of Rheumatology Health Professionals (ARHP) in Washington, D.C. The Company will present 23 abstracts that exemplify Bristol-Myers Squibb's leadership in autoimmune disease. This includes real-world data analyses examining the role of poor prognostic factors, with a focus on anti-cyclic citrullinated protein antibodies (anti-CCP, also known as ACPA), in patients with moderate to severe RA. Bristol-Myers Squibb's ACPA-related research has helped further the understanding of ACPA as a key prognostic factor related to rapidly progressive RA.

Among the data being presented are two real-world data analyses from the ongoing Corrona® RA registry – the largest RA cohort prospectively followed in North America. One analysis showed a significant relationship between poor prognostic factors for RA and work status over 12 months. Patients with the worst prognostic factors were less likely to have a part-time or full-time job compared with those having a better RA prognosis. Despite the association between poor prognostic factors and work limitations, the other analysis found no significant association between the presence of 0-1, 2, or 3+ poor prognostic factors for RA and treatment initiation with a biologic therapy over 12 months, suggesting that poor prognostic status does not currently influence RA treatment decisions.

“These data analyses represent clinically meaningful RA research that enrich our understanding of the disease and suggest an important role for the evaluation of RA patients’ status with regard to poor prognostic factors. Patients with a greater number of poor prognostic factors despite treatment had smaller reductions in clinical disease activity index (CDAI) and were less likely to achieve low disease activity (LDA)/remission following their treatment,” said Joel M. Kremer, M.D., Founder and Chief Medical Officer of the Corrona RA registry, as well as a practicing rheumatologist at Center for Rheumatology, LLP in Albany, NY and Pfaff Family Professor of Medicine at the Albany Medical College. “Findings like these demonstrate how poor prognostic factors may inform the way the rheumatology community approaches the disease.”

Bristol-Myers Squibb will also present data at the ACR/ARHP Annual Meeting from the Phase 4 ACTION (AbataCepT In rOutiNe clinical practice) trial, the first international, prospective study to evaluate long-term ORENCIA retention in real-world settings. This includes an interim analysis which assessed the impact of body mass index (BMI) on treatment retention in biologic-naïve RA patients who were double seropositive for rheumatoid factor (RF) and ACPA at baseline. The results showed that the 12-month ORENCIA retention rate was 78.1% (95% CI, 74.7 to 81.2), and that BMI did not significantly impact retention in ORENCIA patients with poor prognostic factors. In addition, the interim data indicate that RF/ACPA double seropositivity is predictive of ORENCIA retention in biologic-naïve patients, particularly
in patients with erosive disease at baseline.

“Bristol-Myers Squibb is sharing a comprehensive set of trial-based and real-world research at this year’s ACR/ARHP Annual Meeting, supporting the use of ORENCIA in the treatment of RA – particularly for those with rapidly progressing disease and poor prognostic factors,” said Brian J. Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb. “The breadth of these data – in combination with our industry-leading research in biomarkers that affect treatment outcomes – offer meaningful insights into improving patient prognosis and addressing the unmet needs of people living with autoimmune diseases like RA.”

New PsA and pJIA Data Among Bristol-Myers Squibb Presentations at the ACR/ARHP Annual Meeting

In addition to sharing RA-related data, Bristol-Myers Squibb will present new Phase 3 data on the results of abatacept in the treatment of psoriatic arthritis (PsA), as well as polyarticular juvenile idiopathic arthritis (pJIA).

In an oral presentation, investigators will reveal topline results from the ASTRAEA (Active pSoriaTic aRthritis rAndomizEd triAl) study, an international, double-blind, multicenter Phase 3 study evaluating abatacept treatment vs. placebo in 424 patients with PsA. Patients were randomized 1:1 to receive subcutaneous (SC) abatacept 125 mg weekly or placebo for 24 weeks. Treatment with abatacept demonstrated superior efficacy (as measured by ACR20 response) at Week 24 vs. placebo (95% CI, 17.2 (8.7, 25.6) with p<0.001) and maintained efficacy at one year, regardless of previous treatment with a tumor necrosis factor inhibitor (TNFi). More than 60% of patients studied had prior exposure to a TNFi. In addition, the study showed abatacept had a similar safety profile as placebo. Based on these data, BMS has submitted a Supplemental Biologics License Application (sBLA) with the Food and Drug Administration (FDA), as well as a Variation Application (VA) with the European Medicines Agency (EMA) to extend the indication for abatacept to include the treatment of adult PsA.

Researchers also will share an encore oral presentation on Phase 3 abatacept data in pJIA. These data showed that subcutaneous (SC) abatacept had equivalent efficacy and comparable safety to intravenous (IV) abatacept in patients with pJIA. After four months, more than 80% of patients taking SC abatacept achieved an ACR30 response. In addition, SC abatacept showed no new safety signals compared to IV ORENCIA.

Additional research Bristol-Myers Squibb will present at the ACR/ARHP Annual Meeting includes late-breaking data exploring preclinical models of systemic lupus erythematosus and inflammatory bowel disease.

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 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
**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, 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 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 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.

References


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#BMS will present new data in #RheumatoidArthritis and other autoimmune diseases at #ACR16. Learn more:

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