Bristol-Myers Squibb to Showcase Immunoscience Research and Biomarker-Guided Treatment Approaches at the 2018 American College of Rheumatology and Association of Rheumatology Health Professionals Annual Meeting

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- Growing body of evidence, including real-world studies, points to the clinical significance of anti-citrullinated protein antibody (ACPA) as a biomarker of poor prognosis in patients with rheumatoid arthritis (RA)

- AVERT-II data provides new insights into treatment with ORENCIA® (abatacept) in patients with newly diagnosed ACPA-positive RA

- Multiple presentations advance understanding of disease burden and the treatment of a wide spectrum of immune-mediated diseases, including psoriasis, Sjögren's syndrome, lupus nephritis and juvenile idiopathic arthritis; other studies evaluate differential treatment response and health economic data for patients with highly active progressive RA

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that 28 abstracts related to ORENCIA® (abatacept) and the Company’s immunoscience pipeline will be presented at the 2018 American College of Rheumatology and Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting, October 19-24, 2018, in Chicago.

The abstracts accepted for presentation include clinical and real-world ORENCIA data exploring the impact of anti-citrullinated protein antibody (ACPA) as a biomarker of poor prognosis in patients with rheumatoid arthritis (RA) and other autoimmune diseases.

“The breadth and depth of immunoscience data that Bristol-Myers Squibb is presenting at ACR is helping advance scientific understanding of disease pathology and burden in a range of autoimmune diseases, with the potential to inform biomarker-guided treatment decisions,” said Brian Gavin, Ph.D., development lead, Orencia, Bristol-Myers Squibb. “The clinical and real-world data we’re generating suggests that identifying and targeting biomarkers, such as ACPA, could lead to a more personalized treatment approach, particularly among patients with highly active rheumatoid arthritis.”

Among the Bristol-Myers Squibb data to be presented at the 2018 ACR/ARHP Annual Meeting:

- Real-world outcomes evidence that ACPA status is associated with a differential treatment response to abatacept. The analysis will be featured in a poster presentation on Sunday, October 21, at 9:00 a.m. CST.¹

- AVERT-II data providing new insights into treatment with ORENCIA in patients with newly diagnosed ACPA-positive RA. These data will be presented as a poster on Sunday, October 21, at 9:00 a.m. CST.²

- Post-hoc analysis from the ALLURE study looking at the impact of treatment on proteinuria and clinical response at three years. These data will be featured in an oral presentation on Sunday, October 21, at 4:30 p.m. CST.³

- Observational data analysis describing differences seen in patients with RA and Sjögren’s syndrome compared to patients with RA alone, in terms of comorbidities, autoantibody profiles and overall disease burden. Registry data and
analysis will be featured in a poster presentation on Sunday, October 21, at 9:00 a.m. CST.4

- Phase 2 study results of BMS-986165, an oral tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate-to-severe psoriasis (PsO). Skin measures were assessed by Psoriasis Area and Severity Index (PASI) and pain was assessed by ACR pain visual analog scale (VAS). These data will be featured in a poster presentation on Tuesday, October 23, at 9:00 a.m. CST.5

- Real-world data analysis of the incremental cost associated with ACPA positivity by care pathways. This latent class analysis will be featured in an oral presentation on Wednesday, October 24, at 11:00 a.m. CST.6

The full listing of abstracts sponsored by Bristol-Myers Squibb at the 2018 ACR/ARHP Annual Meeting follows. Complete abstracts can be accessed online here.

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<td><strong>Abstract 971:</strong> A phase III randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of abatacept or placebo on standard of care in patients with active class III or IV lupus nephritis</td>
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<td><strong>Abstract 2999:</strong> Does the incremental cost of ACPA-positive rheumatoid arthritis patients vary by the care pathway they follow?</td>
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<td><strong>Abstract 223:</strong> The effect of concomitant diabetes on RA-related outcomes: results from the ACR's RISE registry</td>
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<td><strong>Abstract 265:</strong> Disparities in utilization and direct costs of hospitalizations and emergency room visits in SLE: the Georgia Lupus Registry</td>
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<td><strong>Abstract 541:</strong> Prevalence of Sjögren's syndrome in patients with RA enrolled in a large observational U.S. registry</td>
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<td><strong>Abstract 542:</strong> Incidence and prevalence of interstitial lung disease in U.S. population and in patients with rheumatoid arthritis by anti-CCP status</td>
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<td>Channeling to treatment and associated changes in disease activity over 12 months in patients with RA treated with abatacept versus other DMARDs in real-world community practice settings</td>
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<td>Efficacy and safety of abatacept in combination with methotrexate (MTX) in early, mtx-naive, anti-citrullinated protein antibody-positive patients with RA: primary and 1-year results from a phase IIIb study</td>
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Abstract 2506: The joint disease burden in patients with secondary Sjögren's syndrome and RA compared with patients with RA only

Tuesday, October 23, 2018
9:00 a.m. - 11:00 a.m. CST

Abstract 2507: Healthcare resource utilization in patients with secondary Sjögren's syndrome associated with RA compared with patients with RA in an insured population

Tuesday, October 23, 2018
9:00 a.m. - 11:00 a.m. CST

Abstract 2554: Abatacept without methotrexate in patients with active psoriatic arthritis: a post-hoc analysis of a Phase III, randomized study

Tuesday, October 23, 2018
9:00 a.m. - 11:00 a.m. CST

Abstract 2563: Efficacy and safety of a potent and highly selective oral tyrosine kinase 2 inhibitor, BMS-986165, in patients with moderate-to-severe plaque psoriasis: a phase II, randomized, placebo-controlled trial

Tuesday, October 23, 2018
9:00 a.m. - 11:00 a.m. CST

Abstract 2633: Disease activity, organ damage and patient-reported outcome measures in Swedish patients with recent-onset SLE

Tuesday, October 23, 2018
9:00 a.m. - 11:00 a.m. CST

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a destructive 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 an immunomodulator that disrupts the continuous cycle of T-cell activation that characterizes RA, thereby inhibiting the production of B-cell derived autoantibodies and proinflammatory cytokines.

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 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 JA 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 pyruvoloquinone 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 see Full Prescribing Information at https://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 new 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, 2017 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 or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

References


