Bristol-Myers Squibb to Present Data from 24 Abstracts in Immunoscience at the American College of Rheumatology (ACR) 2015 Congress

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Patient-reported data from post-hoc analyses of the AVERT trial evaluating rate of RAPID3-defined remission and time to remission in early moderate to severe rheumatoid arthritis (RA) patients treated with Orencia (abatacept) + methotrexate (MTX) vs. MTX alone to be presented

New two-year data from AVERT on re-treatment with Orencia plus MTX in recapturing prior remission following a flare after complete therapy withdrawal in patients with early moderate to severe RA also to be presented

Oral presentation on translational research evaluating how different sets of immune cells may correlate with distinct clinical characteristics as well as response to Orencia therapy in patients with systemic lupus erythematosus (SLE)

PRINCETON, N.J. -- (BUSINESS WIRE) -- Bristol-Myers Squibb Company (NYSE:BMY) announced today that 24 abstracts on Orencia (abatacept) and related immunoscience data will be presented at the 2015 annual meeting of the American College of Rheumatology (ACR), to be held November 6-11, in San Francisco, CA. The data being presented reinforce the company's continued commitment to further research in moderate to severe rheumatoid arthritis (RA) and other immune-related diseases.

Two of the highlighted presentations include new data from the Assessing Very Early Rheumatoid Arthritis Treatment (AVERT) study, a Phase 3 trial evaluating patients with early, progressive disease and poor prognosis. One analysis assessed patient-reported outcomes and remission rates as measured by Routine Assessment of Patient Index Data 3 (RAPID3)-defined remission, as well as correlation between RAPID3 and Boolean, SDAI and CDAI (definitions of remission) in each treatment arm. The second analysis of the AVERT data evaluated the re-treatment of moderate to severe RA with Orencia plus MTX after complete therapy withdrawal and rates of disease remission following a flare, as well as rates of achieving a major clinical response (MCR). In addition, an oral presentation during the congress will feature new translational research evaluating how different sets of immune cells may correlate with distinct clinical characteristics and response to Orencia in patients with lupus.

"As a leader in the research of immunomodulatory therapies, Bristol-Myers Squibb is proud to present a broad set of analyses at ACR that will help inform the physician community about Orencia data and the importance of managing patients with early, progressive, moderate to severe RA," said Douglas Manion, M.D., head of Specialty Development, Bristol-Myers Squibb. "At ACR this year, we will also share investigational data on Orencia in other immune-related diseases like lupus, which is estimated to affect more than one million people in the U.S. Bristol-Myers Squibb remains committed to ongoing research that helps to address unmet medical needs of patients in a broad range of autoimmune disorders including myositis, vasculitis and Sjogren's syndrome, among others."

The complete list of Bristol-Myers Squibb presentations is below. Abstracts can be accessed on the ACR website at: http://acrabstracts.org/.
Oral Presentation

De-Convolution of Whole Blood Transcriptomic Data from a Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial of Abatacept in Systemic Lupus Erythematosus  
November 9, 2015 at 2:30 p.m. PST

Poster Presentations

Abatacept Plus Methotrexate Can Effectively and Safely Regain the Target of Remission Following Re-Treatment for Flares after Drug-Free Withdrawal in Patients with Early Rheumatoid Arthritis (AVERT)  
November 8, 2015 at 9:00 a.m. PST

Baseline Autoantibodies Preferentially Impact Abatacept Efficacy in Patients with RA Who Are Biologic Naive: 6-Month Results from a Real-World, International, Prospective Study (ACTION)  
November 8, 2015 at 9:00 a.m. PST

Body Mass Index Does Not Influence the Efficacy of Abatacept in Patients with RA Who Are Biologic Naive: 6-Month Results from a Real-World, International, Prospective Study (ACTION)  
November 8, 2015 at 9:00 a.m. PST

Can Anti-TNF-Induced Autoantibody Conversion be Reversed by Switching to Abatacept Therapy in Patients with RA on Background MTX? (AMPLE, ATTEST)  
November 8, 2015 at 9:00 a.m. PST

Disease and Treatment Characteristics That Might Influence Long-Term Retention with Biologics in the Real-World Clinical Setting: Experience from the Rhumadata Clinical Database and Registry  
November 8, 2015 at 9:00 a.m. PST

First Year Canadian Experience with Subcutaneous Abatacept in Routine Practice for the Treatment of Patients with Rheumatoid Arthritis: Data from the Orencia Response Program (ORP) Network  
November 8, 2015 at 9:00 a.m. PST

Impact of Anti-Citrullinated Protein Antibody Status and Response to Abatacept (CORRONA)  
November 8, 2015 at 9:00 a.m. PST

Impact of Baseline Anti-Cyclic Citrullinated Peptide 2 Antibody Titer on Efficacy Outcomes Following Treatment with Subcutaneous Abatacept or Adalimumab (AMPLE)  
November 8, 2015 at 9:00 a.m. PST

On Drug and Drug-Free Remission by Baseline Disease Duration: Abatacept Versus Methotrexate Comparison in Patients with Early Rheumatoid Arthritis (AVERT)  
November 8, 2015 at 9:00 a.m. PST

Predictors of Real-World Treatment Sustainability in RA Patients Treated with Abatacept in Canada: Implications for Routine Care  
November 8, 2015 at 9:00 a.m. PST

Six-Year Retention Rates with Abatacept Vs TNF Inhibitors in the Treatment of Rheumatoid Arthritis: Experience from the Real-World Rhumadata Clinical Database and Registry  
November 8, 2015 at 9:00 a.m. PST

Tuberculosis Risk Among Patients with Rheumatoid Arthritis in a United States Claims Database Initiating Abatacept and Other Biologic Disease-Modifying Antirheumatic Drugs: Analyses Using International Classification of Diseases Codes and a Published Claims Algorithm  
November 8, 2015 at 9:00 a.m. PST

Drug Survival of Second Biologic DMARD Therapy in Patients with Rheumatoid Arthritis: Comparison of a Second Anti-TNF with a Second Non-Anti-TNF after Discontinuation of a First Anti-TNF  
November 9, 2015 at 9:00 a.m. PST

Evaluation of Changes in Cardiovascular Risk Factors Among Patients with RA Prescribed Biologic DMARDs (HEOR)  
November 9, 2015 at 9:00 a.m. PST

Incidence of Co-Morbid Autoimmune Diseases in Patients with Rheumatoid Arthritis  
November 9, 2015 at 9:00 a.m. PST

Long-Term Effectiveness and Safety of Abatacept in Juvenile Idiopathic Arthritis: Interim Results from the Abatacept in JIA Registry  
November 9, 2015 at 9:00 a.m. PST

Routine Assessment of Patient Index Data 3 (RAPID3)-Defined Remission Is As Stringent As ACR/EULAR Boolean-Defined Remission in a Clinical Trial of Patients with Early Rheumatoid Arthritis Treated with Abatacept  
November 9, 2015 at 9:00 a.m. PST

Baseline Characteristics and Changes in Disease Activity at 12 Months in Patients Treated with Abatacept Versus Other Biologic Disease-Modifying Antirheumatic Drugs in Clinical Practice Setting (BRASS)  
November 10, 2015 at 9:00 a.m. PST
Effect of Anti-Cyclic Citrullinated Peptide 2 Immunoglobulin M Serostatus on Efficacy Outcomes Following Treatment with Abatacept Plus Methotrexate (AVERT)  
November 10, 2015 at 9:00 a.m. PST

Evaluation of Anti-Cyclic Citrullinated Peptide Autoantibody Levels in Clinical Practice and Its Association with Disease Activity (BRASS)  
November 10, 2015 at 9:00 a.m. PST

Evaluation of the Impact of Disease-Modifying Antirheumatic Drugs on Anti-Cyclic Citrullinated Peptide Autoantibody Levels in Clinical Practice (BRASS)  
November 10, 2015 at 9:00 a.m. PST

Evaluation of Patient-Reported Outcomes By Baseline Disease Duration: 6-Month Data from Two Clinical Trials of Patients with Early Rheumatoid Arthritis Treated with Abatacept  
November 10, 2015 at 9:00 a.m. PST

Is Disease Duration an Independent Predictor of Treatment Response Among Patients with Rheumatoid Arthritis Initiating Abatacept? (CORRONA)  
November 10, 2015 at 9:00 a.m. PST

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 Systemic Lupus Erythematosus

Systemic Lupus Erythematosus (SLE) is a chronic, autoimmune disease characterized by inflammation of the skin and joints and can affect other organs in the body such as the kidneys, and tissue lining the lungs, heart, and brain. The condition occurs 10 times more often in women and commonly begins developing in people in their 20s and 30s.

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)

Indications/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 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

Concomitant Use with TNF Antagonists: Concurrent therapy with ORENCIA® (abatacept) 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® (abatacept) 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® (abatacept).

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 parents be brought up to date with all immunizations in agreement with current immunization guidelines before 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 exacerbations, 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%) vs 0.1% (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.

Pregnant and Nursing Mothers: ORENCIA should be used during pregnancy only if clearly needed. The risk for development of autoimmune diseases in humans exposed in utero to abatacept has not been determined. Nursing mothers should be informed of the risk/benefit of continued breast-feeding or discontinuation of the drug. A pregnancy registry has been established to monitor fetal outcomes. Healthcare professionals are encouraged to register pregnant patients exposed to ORENCIA by calling 1-877-311-8972.

Most Serious Adverse Reactions: Serious infections (3% ORENCIA® (abatacept) 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 U.S. Full Prescribing Information for ORENCIA.

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

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 www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

About Bristol-Myers Squibb Immunoscience

With a robust pipeline of immunomodulatory therapies, Bristol-Myers Squibb is committed to the discovery and development of transformative 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.

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, 2014 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.

Language:
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Contact:
Bristol-Myers Squibb Company
Media:
Shelly Mittendorf, 609-480-2951
shelly.mittendorf@bms.com
or
Investors:
Ranya Dajani, 609-252-5330
ranya.dajani@bms.com
or
Bill Szablewski, 609-252-5894
william.szablewski@bms.com

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