Bristol-Myers Squibb to Present New Research Findings on the Treatment of Patients with Early Rheumatoid Arthritis at the Annual European Congress of Rheumatology (EULAR 2018)

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Multiple presentations explore anti-citrullinated protein antibody (ACPA) as a biomarker of poor prognosis for patients with rheumatoid arthritis (RA)

Research provides additional insights into the immune-modulating role of ORENCIA® (abatacept) therapy, including in biologic-naive patients

PRINCETON, N.J. -- (BUSINESS WIRE) -- Bristol-Myers Squibb Company (NYSE: BMY) today confirmed that 31 abstracts demonstrating The Company’s immunoscience-research focus as well as how ORENCIA® (abatacept) therapy may impact diverse patient subgroups will be presented at the Annual European Congress of Rheumatology (EULAR 2018), June 13-16 in Amsterdam.

For more than two decades, Bristol-Myers Squibb has pioneered research into the body’s immune system aimed at discovering and developing medicines that harness immunomodulation to treat disease. The data to be presented at EULAR 2018 include analyses that provide new insights into immunomodulation treatment for RA with ORENCIA, as well as research that further explores the clinical significance of ACPA, particularly as a predictive biomarker indicative of a poor prognosis for patients with early highly active, progressive RA.

Among the Bristol-Myers Squibb data to be presented at EULAR 2018:

- Claims analysis demonstrating an association between patients with RA presenting elevated ACPA titers are susceptible to increased mortality rates in a real world setting. The full post hoc analysis will be featured in an oral presentation on Thursday, June 14, at 11:10 CEST.
- Analysis comparing abatacept with adalimumab on measures of sustained remission [DAS28 (CRP) <2.6] and showing seropositive patients with early, erosive RA may respond differently to targeted biologic therapy. The full post hoc analysis will be featured in a poster presentation on Saturday, June 16, from 10:30-12:00 CEST.
- Claims analysis (2006–2016) of abatacept-treated RA patients with greater risk factors for type 2 diabetes at baseline evaluating the risk for new-onset type 2 diabetes versus patients treated with other biological disease-modifying, anti-rheumatic drugs (bDMARDs). The full data analysis will be featured in a poster presentation on Thursday, June 14, from 11:45–13:30 CEST.
- Real-world data looking at the risk for infection-related hospitalization and associated medical costs for patients in the United States treated with abatacept versus other targeted disease-modifying, anti-rheumatic drugs (tDMARDs). The full data analysis will be featured in a poster presentation on Thursday, June 14, from 11:45-13:30 CEST.

“The research that Bristol-Myers Squibb is presenting at EULAR 2018 speaks to our focus on helping address the burden of destructive autoimmune diseases for patients and physicians,” said Brian Gavin, PhD, Development Lead, Orencia & Nulojix, Bristol-Myers Squibb. “We are building on a 20-year research commitment to defining the role of immunomodulation in treating autoimmune diseases and researching clinically meaningful biomarkers that can help guide personalized treatment approaches to conditions like rheumatoid arthritis.”

The full listing of abstracts Bristol-Myers Squibb will present at EULAR 2018, including data and analyses in rheumatoid arthritis, juvenile idiopathic arthritis, lupus nephritis and other disease types follows. Complete abstracts can be accessed online here.
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<th>Abstract Title</th>
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<td><strong>Oral Presentations</strong></td>
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<tr>
<td><strong>OP0010</strong>: Use of Claims and Electronic Medical Record Data to Predict RA Disease Activity</td>
<td>Wednesday, June 13 15:30 CEST</td>
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<td><strong>OP0195</strong>: Role of Seropositivity on Mortality in RA and the Impact of Treatment with DMARDS</td>
<td>Thursday, June 14 11:10 CEST</td>
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<td><strong>OP0130</strong>: Risk of Cancer in Patients with Psoriasis/Psoriatic Arthritis: A Population-Based Study in the Province of British Columbia</td>
<td>Thursday, June 14 11:10 CEST</td>
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<td><strong>OP0227</strong>: Timing of Abatacept Before Elective Arthroplasty and Post-Operative Outcomes</td>
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<td><strong>OP0228</strong>: Comparative Risk of Biologic Therapies and Risk of Glucocorticoids in Patients with Rheumatoid Arthritis Undergoing Elective Arthroplasty</td>
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<td><strong>OP0253</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>
<td>Friday, June 15 10:50 CEST</td>
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<td><strong>Poster Tours</strong></td>
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<td><strong>THU0549</strong>: Absence of Association Between Drug Exposure and Infection in Patients with Polyarticular-Course Juvenile Idiopathic Arthritis and Inadequate Response to Biologic or Non-Biologic DMARDS Treated with SC and IV Abatacept</td>
<td>Thursday, June 14 11:45–13:30 CEST</td>
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<td><strong>FR10044</strong>: Exceeding Predefined Thresholds for MRI Bone Oedema and Erosion and HAQ-DI Can Predict Relapse After Withdrawal of All Treatment in MTX-Naïve Patients with RA in Remission After 12 Months of Abatacept Therapy in the AVERT Trial</td>
<td>Friday, June 15 11:45–13:30 CEST</td>
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<td><strong>FR10740-HPR</strong>: Responding Resiliently to Chronic Disease: Rheumatoid Arthritis Patients’ Discourse on Coping Strategies and Challenges</td>
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<td><strong>Poster Presentations</strong></td>
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<td><strong>THU0668</strong>: Choice of Initial Biologic Disease-Modifying Antirheumatic Drug Impacts Healthcare Resource Use Among Patients with Rapidly Progressing Rheumatoid Arthritis</td>
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<td><strong>THU0221</strong>: Clinical Outcomes of Abatacept Versus TNF Inhibitors in ACPA-Positive Patients with Rheumatoid Arthritis: Data from the Biologic Register KOBIO</td>
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<td><strong>THU0640</strong>: Pharmacological Treatment among Newly Diagnosed Patients with Juvenile Idiopathic Arthritis in the United States</td>
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<td><strong>THU0688</strong>: Do Certain DMARDS Increase Risk of New-Onset Type 2 Diabetes? Evaluation of Patients’ Baseline Characteristics</td>
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<td><strong>THU0312</strong>: Risk of Infection in Patients with Psoriasis/Psoriatic Arthritis: A Population-Based Study in the Province of British Columbia</td>
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<td><strong>THU0645</strong>: Impact of Second-Line Therapy with Abatacept Versus Other Targeted DMARDS on the Risk for Infection-Related Hospitalizations and Associated Costs Among RA Patients in the United States</td>
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<td><strong>FR10139</strong>: Comparative Safety of Abatacept in Rheumatoid Arthritis with COPD: A Real-World Population-Based Observational Study</td>
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<td><strong>FR10725-HPR</strong>: Understanding the Burden of Rheumatoid Arthritis Using Qualitative Research: Which Impacts Are Not Captured by Patient-Reported Measures?</td>
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<td><strong>FR10347</strong>: Performance of Potential Definitions of Remission in Systemic Lupus Erythematosus (SLE) Versus Quality of Life over Five Years in Swedish Patients with Recent-Onset SLE</td>
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<td><strong>SAT0108</strong>: Efficacy of Abatacept Versus Adalimumab on the Proportion of Patients with Seropositive, Erosive Early RA Achieving DAS28 (CRP) &lt;2.6 or Validated Measures of Remission: A Post Hoc Analysis of the Two-Year AMPLE Trial</td>
<td>Saturday, June 16 10:30–12:00 CEST</td>
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<td><strong>SAT0133</strong>: Prevalence of Type 2 Diabetes and Evaluation of Patient Characteristics among Patients with and without RA from Community Rheumatology Clinics</td>
<td>Saturday, June 16 10:30–12:00 CEST</td>
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SAT0453: Association of Comorbid Pulmonary Conditions with Patient-Reported Outcomes in Systemic Lupus Erythematosus (SLE)  Saturday, June 16 10:30–12:00 CEST

SAT0098: Patient and Disease Characteristics that Predict Switching from a TNF Inhibitor to Another Biologic or Targeted Synthetic DMARD in Patients with RA in Clinical Practice  Saturday, June 16 10:30–12:00 CEST

SAT0126: Characterizing Heterogeneous Care Pathways of Incident Rheumatoid Arthritis Patients  Saturday, June 16 10:30–12:00 CEST

Book Only

- Impact of Work Status on Health-Related Quality of Life (HRQOL) in RA  NA
- Association of Shared Epitope and Poor Prognostic Factors in RA  NA
- Up to Five-Year Retention of Abatacept in Belgian Patients with Moderate-to-Severe RA: Prospective Data from the Real-World ACTION Study  NA
- Identification of Joint Locations That Are Poor Prognostic Indicators and Require More Intensive Therapy in an Early, Rapidly Progressing RA Cohort: A Post Hoc AGRE Analysis  NA
- Experience with Subcutaneous Abatacept in Routine Clinical Practice: Six-Month Interim Analysis of a Two-Year, Prospective, Non-Interventional, Multicenter Study in Patients with RA  NA
- Association Between Anti-Citrullinated Protein Antibody Status, Erosive Disease and Healthcare Resource Utilization in Patients with RA  NA
- Understanding Fatigue Burden and Coping Strategies in Rheumatoid Arthritis Using Qualitative Research  NA
- Comparative Safety of Abatacept vs Tofacitinib in Adults with Moderate-to-Severe RA: A Systematic Literature Review and Network Meta-Analysis  NA

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a destructive autoimmune disease characterized by inflammation in the lining of joints (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)

**U.S. 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® (abatacept) is indicated for reducing signs and symptoms in patients aged 2 years of age 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 RA 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 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 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 ORENCIA administration options: Intraavenous 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 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. Among other risks, there can be no guarantee that Opdivo or Yervoy will receive regulatory approval for an additional indication. 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 any forward-looking statement, whether as a result of new information, future events or otherwise.

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English

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