Bristol-Myers Squibb To Present New Research Related to the Treatment of Rheumatoid Arthritis Patients With Highly Active, Progressive Disease at the Annual European Congress of Rheumatology (EULAR 2017)

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Dateline City:
PRINCETON, N.J.

Key analyses focus on treatment outcomes among RA patients with a traditionally poor prognosis

ORENCIA ® (abatacept) continuing research underscores Bristol-Myers Squibb’s commitment to advancing the science of modulating the body’s immune response to treat disease

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today confirmed that 23 abstracts related to ORENCIA® (abatacept), including new data on the role of biomarkers and MRI in RA patient identification and treatment, will be presented at the Annual European Congress of Rheumatology (EULAR 2017), June 14-17 in Madrid, Spain. The Company also will share first-in-human data from BMS-986165, an investigational TYK2 inhibitor.

Bristol-Myers Squibb has played a leading role for more than two decades in discovering and developing medicines designed to help modulate the body’s immune response to treat disease. The abstracts from Bristol-Myers Squibb accepted for EULAR 2017 include three practice-informing analyses pertaining to ORENCIA treatment responses in patients with highly active, progressive rheumatoid arthritis (RA), who traditionally have a poor prognosis.1-3

- A post hoc analysis of the phase 3 AGREE* clinical trial showing that among patients with early, erosive RA, treatment with ORENCIA + MTX (vs. MTX alone) resulted in higher seroconversion rates.2 Seroconversion refers to the RA autoantibodies ACPA and RF - anti-citrullinated protein antibodies and rheumatoid factor - falling to undetectable levels among patients who entered the trial with measurable (seropositive) levels.2 ACPA and RF are biomarkers associated with poor prognosis in RA.2 The full data analysis will be featured in a poster tour on Friday, June 16, from 11:45 – 13:30 CET.

- A post hoc analysis of the phase 3b AVERT** study (MTX versus Orencia+MTX) evaluating the proportion of patients achieving remission at 12 months as measured by baseline MRI-detected inflammation status.3 The analysis explored the response of patients with higher inflammation levels at baseline – as measured by MRI - versus patients with lower baseline levels.3 The full data analysis will be featured in an oral presentation on Friday, June 16, at 10:30 CET.

- A post hoc analysis of the phase 3b AMPLE*** study that investigated the efficacy of ORENCIA+MTX versus the TNF inhibitor adalimumab+MTX in patients with seropositive, erosive early RA.1 The analysis looked at differences in treatment effect between the two regimens among patients with seropositive, erosive early RA. The full data analysis will be featured in a poster tour on Saturday, June 17, from 10:15 - 12:00 CET.

“The research Bristol-Myers Squibb is presenting at EULAR 2017 shows our commitment to advancing scientific understanding of how biomarkers and tools, such as MRI, can be used to guide patient selection and treatment in highly active, progressive rheumatoid arthritis,” said Brian J. Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb. “Importantly, the research also yields critical insights into the role of modulating the body’s immune system in rheumatoid arthritis and potentially other autoimmune conditions where we are committed to making a meaningful, positive impact on patients’ lives.”

In RA, the body’s immune system mistakenly attacks the joints.4 The costimulation blockade of ORENCIA prevents T-cell
activation and the resulting cascade of events that contribute to joint destruction.

The full listing of abstracts Bristol-Myers Squibb will present at EULAR 2017, including data and analyses in rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis, follows. Complete abstracts can be accessed online here.

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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 Orencia

Orencia 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 is indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis. Orencia may be used as monotherapy or concomitantly with methotrexate (MTX).

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 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 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 pyruvokinase 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:** Intravenous dosing has not been studied in patients younger than 6 years of age. The safety and efficacy of ORENCIA ClickJet Autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.


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 transformative 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, 2016 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.*

*Abatacept study to Gauge Remission and joint damage progression in MTX-naive patients with Early R erosive RA

**Assessing Very Early Rheumatoid Arthritis Treatment

***Abatacept versus Adalimumab ComParison in Biologics-Naïve RA Subjects with Background Methotrexate
References


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English

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