AVERT Trial Demonstrates High Rates of DAS-defined Remission with Orencia® (abatacept) in Combination with Methotrexate (MTX) in Adult Patients with Early Rheumatoid Arthritis (RA)

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- First line therapy with Orencia plus MTX resulted in 60.9% of patients with early RA achieving DAS-defined remission at month 12 of treatment
- Additional analysis of Boolean, CDAI, and SDAI remission, more clinically stringent measures of remission, also showed high remission rates for Orencia plus MTX
- AVERT provides further evidence supporting use of Orencia plus MTX as first line biologic therapy for RA

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today its first release of new data from a Phase IIIb RA trial showing that the T-cell co-stimulation modulator, Orencia® (abatacept), in combination with methotrexate (MTX) achieved significantly higher rates of DAS-defined (DAS28 CRP <2.6) remission at 12 months than treatment with standard of care agent MTX (60.9% vs. 45.2%, respectively), in biologic and MTX-naïve patients with early active RA. The data are being presented this week at the 2014 annual meeting of the European League Against Rheumatism (EULAR).

In this trial, known as AVERT (Assessing Very Early Rheumatoid arthritis Treatment), a co-primary endpoint assessed maintenance of remission following the withdrawal of all RA drug therapy including Orencia, MTX and steroids. A small but statistically significantly higher number of patients treated with Orencia plus MTX, versus MTX alone, for 12 months maintained remission 6 months after all RA treatment was withdrawn.

Orencia was well tolerated in the study patients. In particular, serious adverse events, serious infection events and discontinuation due to serious adverse events were comparable to patients treated with MTX.

“Remission of both clinical symptoms and radiographic joint damage is an important and achievable goal in the management of rheumatoid arthritis, particularly in the early disease phase,” said Paul Emery, M.D., Arthritis Research UK Professor of Rheumatology and Head of the Academic Division of Musculoskeletal Disease, Leeds Institute of Molecular Medicine, University of Leeds, United Kingdom. “Data from the AVERT trial show that patients taking a combination of Orencia plus methotrexate achieved higher rates of remission than treating them with methotrexate alone. Interestingly, this benefit was maintained in some patients even after all RA treatment had been withdrawn.”

“These data demonstrating higher remission rates and a similar safety profile for Orencia plus methotrexate versus methotrexate alone, in conjunction with insights from the withdrawal phase of the study, support the use of Orencia as a first line biologic therapy for patients with RA,” said Michael Giordano, senior vice president, head of development, Oncology and Immunology, Bristol-Myers Squibb.

Data from the AVERT Trial

AVERT is a Phase IIIb, active-controlled study including 351 adult patients with symptoms of RA for less than two years, positive for anti-CCP antibodies, DAS28 CRP >3.2 and naïve to treatment with methotrexate and biologic therapies for RA. The patients were randomly assigned to 12 months of weekly treatment in one of three groups: Orencia 125 mg subcutaneous plus MTX; Orencia 125 mg subcutaneous alone; or MTX alone. Participants who had a DAS28 CRP <3.2 (indicating low disease activity) after the 12-month treatment phase were able to continue in a withdrawal period up to 12 months, where all RA treatment including Orencia, MTX and steroids were withdrawn. The co-primary endpoints compared the proportion of patients with DAS28 CRP <2.6 (defined as disease remission in the trial) at month 12 and both months 12 and 18 for combination therapy versus MTX alone.

At 12 months, significantly more patients on Orencia combination therapy achieved DAS28-defined remission (60.9%,
OREncia® (abatacept) is a prescription medicine that reduces signs and symptoms in adults with moderate to severe rheumatoid arthritis (RA), including those who have not been helped enough by other medicines for RA. OREncia may prevent further damage to your bones and joints and may help your ability to perform daily activities. In adults, OREncia may be used alone or with other RA treatments other than tumor necrosis factor (TNF) antagonists.

Juvenile Idiopathic Arthritis (JIA): OREncia also reduces signs and symptoms in children and adolescents 6 years of age and older with moderate to severe polyarticular juvenile idiopathic arthritis (JIA). OREncia may be used alone or with methotrexate (MTX).

**Important Safety Information About OREncia® (abatacept)**

Inform your healthcare provider of the following, before you receive treatment with OREncia:

**Infections:** If you have any kind of infection, even if it is small (such as an open cut or sore), an infection that is in your whole body (such as the flu), an infection that will not go away, or a history of infections that keep coming back. OREncia may make your immune system less able to fight infections, so you may be more likely to get infections or any infection you have may get worse.

**Tuberculosis:** If you have had tuberculosis (TB), a positive skin test for TB, or if you recently have been in close contact with someone who has had TB. If you get any of the symptoms of TB (a dry cough that does not go away, weight loss, fever, night sweats), call your healthcare provider right away. Before you start OREncia, your healthcare provider may examine you for TB or perform a skin test.
If you have or have had Viral Hepatitis. Before you use ORENCIA, your healthcare provider may examine you for hepatitis.

If you have a history of Chronic Obstructive Pulmonary (lung) Disease (COPD).

If you are scheduled to have Surgery.

**Allergies to the Ingredients of ORENCIA® (abatacept):** The ingredients of intravenous (IV) ORENCIA are: abatacept, maltose, monobasic sodium phosphate, and sodium chloride for administration. The ingredients of subcutaneous (SC) ORENCIA are: abatacept, sucrose, poloxamer 188, monobasic sodium phosphate monohydrate, dibasic sodium phosphate anhydrous, and water for injection.

**Vaccinations:** If you have recently received a vaccination or are scheduled for any vaccination. If you are receiving ORENCIA, and for 3 months after you stop receiving ORENCIA, you should not take live vaccines.

**Diabetes:** If you have diabetes and use a blood glucose monitor to check your sugar levels. The Infusion of ORENCIA contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day you receive your infusion. Your healthcare provider may tell you to use a different way to monitor your blood sugar levels. ORENCIA for SC injection does not contain maltose; therefore, you do not need to change the way you monitor your blood sugar if you are taking ORENCIA subcutaneously.

**Pregnancy:** If you are pregnant, planning to become pregnant, or are thinking about becoming pregnant. It is not known if ORENCIA can harm your unborn baby.

**Breastfeeding:** You will need to decide to either breast-feed or receive treatment with ORENCIA, but not both.

If you Take Any Other Kinds of Medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements.

If you are Taking Other Biologic Medicines to Treat RA such as: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra), Rituxan® (rituximab), Simponi® (golimumab), Cimzia® (certolizumab pegol), Actemra® (tocilizumab). You may have a higher chance of getting a serious infection if you take ORENCIA with other biologic medicines.

**Possible Side Effects of ORENCIA® (abatacept)**

ORENCIA can cause serious side effects including:

- **Serious infections.** ORENCIA can make you more likely to get infections or make the infection that you have get worse. Some patients have died from these infections. Call your healthcare provider immediately if you feel sick or get any of the following signs of infection: fever; feel very tired; cough; feel flu-like; or warm, red or painful skin.
- **Allergic reactions.** Allergic reactions can happen on the day of treatment or the day after receiving ORENCIA. Tell your healthcare provider or get emergency medical help right away if you have hives; swollen face, eyelids, lips, or tongue; or trouble breathing.
- **Hepatitis B infection.** If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use ORENCIA. Your healthcare provider may do a blood test before you start or while using ORENCIA.
- **Vaccinations.** You should not receive ORENCIA® (abatacept) with certain types of vaccines. ORENCIA may cause some vaccinations to be less effective.
- **Respiratory problems in patients with COPD.** You may get certain respiratory problems more often if you receive ORENCIA and have COPD, including: worsened COPD, pneumonia, cough, or trouble breathing.
- **Cancer (malignancies).** Certain kinds of cancer have been reported in patients receiving ORENCIA. It is not known if ORENCIA increases your chance of getting certain kinds of cancer.

**Common side effects** with ORENCIA are headache, upper respiratory tract infection, sore throat, and nausea. Other side effects in children and adolescents may include diarrhea, cough, fever, and abdominal pain.

**Note concerning use in children under 18 years of age:** ORENCIA for SC injection has not been studied in children under 18 years of age; therefore it is not known if ORENCIA for SC injection is safe and effective in children under 18 years of age.

**Please read the Patient Information in the Full US Prescribing Information.**

**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](http://www.bms.com), or follow us on Twitter at [http://twitter.com/bmsnews](http://twitter.com/bmsnews).

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

**About Bristol-Myers Squibb Immunoscience**

The immune system is the body's natural defense against disease. These processes come into play in almost every human disease. That is why Bristol-Myers Squibb is focused on exploring ways to harness the body's own immune system to treat immune-related diseases with high unmet medical needs, including RA – a chronic, systemic, inflammatory autoimmune...
disorder that affects the joints.

**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, 2013 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:**
English

**Contact:**

**Media:**
Chris Clark, 609-252-6269
chris.clark@bms.com

or

**Investors:**
Bristol-Myers Squibb
Ranya Dajani, 609-252-5330
ranya.dajani@bms.com

or

Ryan Asay, 609-252-5020
ryan.asay@bms.com

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