Bristol-Myers Squibb to Present Data from 14 Abstracts on Orencia (abatacept) at the European League Against Rheumatism (EULAR) 2015 Annual Meeting

Release Date:
Wednesday, June 3, 2015 8:00 am EDT

Terms:
Dateline City:
PRINCETON, N.J.

Presentations include post-hoc analyses of the safety and efficacy of Orencia in anti-citrullinated protein antibodies-positive (ACPA+) highly-active early moderate to severe rheumatoid arthritis (RA) patients from the Phase 3 AVERT study.

New exploratory data from the two-year head-to-head Phase 3 AMPLE trial, evaluating Orencia vs. adalimumab in ACPA+ moderate to severe RA patients also to be presented.

Results from nine other abstracts to be published in EULAR’s program book.

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that 14 abstracts on Orencia have been accepted for presentation at the 2015 annual meeting of the European League Against Rheumatism (EULAR), to be held June 10-13 in Rome, Italy. Several of this year’s abstracts will focus on the safety and efficacy of Orencia in rheumatoid arthritis (RA) patients with anti-citrullinated protein antibodies (ACPA), which is a marker of worse prognosis and more progressive disease.

“Biologic markers, like ACPA, are key to helping rheumatologists diagnose RA patients earlier in the disease process,” said Douglas Manion, M.D., Head of Specialty Development, Bristol-Myers Squibb. “As a leader in immunoscience, Bristol-Myers Squibb is proud to present new results at EULAR that will provide further data on the activity of Orencia in this patient population.”

The complete list of Bristol-Myers Squibb presentations is below.

<table>
<thead>
<tr>
<th>Title</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Presentation</td>
<td></td>
</tr>
<tr>
<td>The Impact of Rheumatoid Arthritis on Patient Reported Outcomes and</td>
<td>June 12, 2015 at 10:35 a.m. CET</td>
</tr>
<tr>
<td>Quality of Life Prior to Biologic Initiation (CORRONA)</td>
<td></td>
</tr>
<tr>
<td>Poster Presentations</td>
<td></td>
</tr>
<tr>
<td>Cost Effectiveness Analysis of Abatacept Compared with Adalimumab on</td>
<td>June 11, 2015 at 12:00 p.m. CET</td>
</tr>
<tr>
<td>Background Methotrexate in Biologic-Naive RA Adult Patients By Anti-cyclic</td>
<td></td>
</tr>
<tr>
<td>Citrullinated Peptide-Positive Subgroups (AMPLE)</td>
<td></td>
</tr>
<tr>
<td>In Patients with Rheumatoid Arthritis and an Inadequate Response to</td>
<td>June 11, 2015 at 12:00 p.m. CET</td>
</tr>
<tr>
<td>Methotrexate, Does Body Mass Index Influence the Efficacy of Abatacept</td>
<td></td>
</tr>
<tr>
<td>on Inflammation When Measured by Power Doppler Ultrasonography? Results from the APPRAISE Study</td>
<td></td>
</tr>
<tr>
<td>Characteristics of Patients Initiating Abatacept for the Treatment of Rheumatoid Arthritis in the Real World: Methodological Challenges for Comparative Safety Studies (-488 Baseline Data)</td>
<td>June 11, 2015 at 12:00 p.m. CET</td>
</tr>
</tbody>
</table>
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 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 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 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%)] 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 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.


**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, 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:** English

**Contact:**

Bristol-Myers Squibb Company
Media:
Kirby Hosea, 609-419-5071
[kirby.hosea@bms.com](mailto:kirby.hosea@bms.com)
or
Investors:
Ranya Dajani, 609-252-5330
[ranya.dajani@bms.com](mailto:ranya.dajani@bms.com)
or
Bill Szablewski, 609-252-5894
[william.szablewski@bms.com](mailto:william.szablewski@bms.com)

**Ticker Slug:**

*Ticker: BMY*
*Exchange: NYSE*