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Subcutaneous (SC) formulation of ORENCIA® (abatacept) Results of Year Two Data from AMPLE Study in Patients with Moderate to Severe Rheumatoid Arthritis Presented at the European League Against Rheumatism (EULAR) Annual Congress

Bristol-Myers Squibb Company (hereinafter referred to as "BMY") announced the results of year two data from AMPLE Study in patients with moderate to severe rheumatoid arthritis was presented at the annual congress of the European League Against Rheumatism (EULAR) ,on June 11th 2013(US time).

Attached from the following page is the press release made by BMY for your information.

Collaboration between Ono and BMKK(Bristol Myers K.K.)

Ono and BMKK concluded an agreement to jointly promote ORENCIA® in September 21, 2011, and, commenced co-promotion on June 4, 2013. The two companies have also been co-developing ORENCIA®. With ORENCIA® IV and ORENCIA® SC, we will further contribute to the treatment of rheumatoid arthritis.

Bristol-Myers Squibb

ORENCIA® (abatacept) Shows Comparable Efficacy to Humira® (adalimumab) in Year Two Data from Head-to-Head Study in Patients with Moderate to Severe Rheumatoid Arthritis

AMPLE Study results highlighted during a press conference at the European League Against Rheumatism (EULAR) Annual congress

- ***Year 2 data shows similar efficacy between ORENCIA plus methotrexate (MTX) and Humira plus MTX, consistent with the year 1 result which demonstrated comparable efficacy based on a non-inferiority endpoint for ACR 20 response***
- ***Radiographic non-progression at 2 years was achieved by 85 percent of patients on ORENCIA plus MTX and 84 percent of patients on Humira plus MTX***
- ***The frequency of adverse events was overall similar in both groups; there were numerically fewer discontinuations due to adverse events, serious adverse events, serious infections, and fewer local injection site reactions in patients treated with ORENCIA plus MTX***

(PRINCETON, N.J., June 11, 2013) - Bristol-Myers Squibb Company (NYSE: BMY) today announced the results of year two data from AMPLE (**A**batacept Versus Adali**m**umab Com**p**arison in Bio**l**ogic-Naïv**e** rheumatoid arthritis (RA) Subjects With Background Methotrexate), a first-of-its-kind trial of 646 patients comparing the subcutaneous (SC) formulation of ORENCIA® (abatacept) vs. Humira® (adalimumab), each on a background of MTX, in biologic naïve patients with moderate to severe RA. The AMPLE year two data are being presented this week at the European League Against Rheumatism (EULAR) annual congress and highlighted during a congress press conference.

AMPLE met its primary endpoint as measured by non-inferiority of ACR20 (American College of Rheumatology 20 percent improvement) at year one. The ORENCIA regimen achieved comparable rates of efficacy vs. the Humira regimen (64.8% vs. 63.4%, respectively). Onset of response was also generally similar for the two groups.

Year two of the study remained investigator-blinded. At year two, the ORENCIA regimen achieved the same rate of efficacy (60%) as the Humira regimen based on ACR20. ACR50, 70, and 90, considered to be more stringent measures of efficacy, as well as DAS-28-CRP, were assessed over 24 months and were generally similar for the two arms.

Radiographic progression was also assessed at two years with 85% of patients on the ORENCIA regimen and 84% of patients on the Humira regimen achieving radiographic non-progression.

"Results from the second year of the AMPLE study confirm what we saw in year one data," said Michael Schiff, M.D., M.A.C.R., University of Colorado, and principal AMPLE study investigator, "namely, that efficacy was comparable for the two agents in this study."

At 24 months, overall safety data were similar for both groups, including frequency of adverse events (92.8% and 91.5%), serious adverse events (13.8% and 16.5%), and malignancies (2.2% and 2.1%) for the ORENCIA regimen and the Humira regimen, respectively. Discontinuations due to adverse events were 3.8% for the ORENCIA regimen and 9.5% for the Humira regimen, while discontinuations due to serious adverse events were 1.6% for the ORENCIA regimen and 4.9% for the Humira regimen. Additionally, zero of the 12 patients who experienced serious infections in the ORENCIA group discontinued, while nine of the 19 patients who experienced serious infections in the Humira group discontinued. Autoimmune events, of mild or moderate severity, were reported in 3.8% of patients in the ORENCIA group and 1.8% of patients in the Humira group. Injection site reactions were reported in 4.1% of patients taking the ORENCIA regimen and 10.4% of patients taking the Humira regimen.

"The two year follow-up data from AMPLE provide important information on the clinical profile of abatacept (ORENCIA) plus MTX as a first biologic treatment option for patients with severe to moderate RA," said Dr. Schiff.

About the Study

AMPLE is a phase IIIb randomized, investigator-blinded multinational study of 24 months duration with a 12 month efficacy primary endpoint (non-inferiority for ACR20). The study included 646 adult biologic-naïve patients with active moderate to severe RA and inadequate response to MTX; 318 in the ORENCIA plus MTX group and 328 in the Humira plus MTX group. Patients were stratified by disease activity and randomized to either 125 mg

ORENCIA SC weekly or 40 mg Humira every other week, both on background MTX. The primary endpoint was to determine non-inferiority of ORENCIA plus MTX to Humira plus MTX based on ACR20 response at 12 months. Secondary endpoints included injection site reactions, radiographic non-progression as assessed using the van der Heijde modified total Sharp score (mTSS) method, safety and retention. The complete year one study results were published in the January 2013 volume of *Arthritis & Rheumatism*, the official monthly journal of the American College of Rheumatology.

Detailed Study Results

Of 646 patients who were randomized and treated, 79.2% (252 of 318) ORENCIA plus MTX patients and 74.7% (245 of 328) Humira plus MTX patients completed the full 24 month study.

Comparable ACR20 response rates at year two were 59.7% for ORENCIA plus MTX and 60.1% for Humira plus MTX.

Onset of response was also generally comparable between the two groups for ACR20, 50 and 70 with responses remaining comparable through two years.

Additionally, 30.2% patients in both treatment groups showed a major clinical response (an ACR70 score maintained for ≥6 months) at two years. A DAS28-CRP score ≤3.2 was achieved by 65.3% of ORENCIA plus MTX patients and 68.0% of HUMIRA plus MTX patients, while 50.6% of ORENCIA plus MTX and 53.3% of HUMIRA plus MTX achieved a score <2.6.

Paired radiographic images were available at baseline and year two for 80.8% (257/318) and 79.3% (260/328) of patients in the ORENCIA plus MTX and Humira plus MTX groups respectively. The distribution of change in total score from baseline to year two showed that inhibition of radiographic damage was similar in both treatment groups, and included most patients. Inhibition of radiographic progression was seen in both component scores (Erosion Score: 0.4 ± 2.6 and 0.4 ± 5.0; Joint Space Narrowing Score: 0.5 ± 2.2 and 0.7 ± 3.8) in the ORENCIA plus MTX and Humira plus MTX groups respectively. At year two, the non-progression rate (change from baseline ≤SDC =2.2) was 84.8% and 83.8% in the ORENCIA plus MTX and Humira plus MTX groups respectively.

At year two, the cumulative rates of adverse events (AEs) were 92.8% and 91.5%, and serious adverse events were 13.8% and 16.5%, in the ORENCIA plus MTX and Humira plus MTX groups, respectively. Discontinuations due to AEs occurred in 3.8% and 9.5% of the ORENCIA plus MTX and Humira plus MTX patients respectively (estimate of difference: -5.7 [95%CI: -9.5, -1.9]). Discontinuations due to SAEs occurred in 1.6% and 4.9% in the ORENCIA plus MTX and Humira plus MTX groups respectively (estimate of difference: -3.3 [95%CI: -9.5, -1.9]). One death occurred in each treatment group, neither of which was attributed to the study medications. Overall, 76.1% of the ORENCIA plus MTX patients and 71.3% of the Humira plus MTX patients had an infection over two years. During the study period, serious infections occurred in 12 (3.8%) and 19 (5.8%) patients of which five and 10 occurred during year two, for ORENCIA plus MTX vs. Humira plus MTX, respectively. Discontinuations due to serious infections were zero of the 12 patients with serious infections for Orencia plus MTX compared to nine of the 19 patients with serious infections, for Humira plus MTX. Injection site reactions were reported in 4.1% of patients taking ORENCIA plus MTX and 10.4% of patients taking Humira plus MTX over two years. Autoimmune events, of moderate or mild severity, were reported in 12 patients (3.8%) in the ORENCIA plus MTX group and six patients (1.8%) in the Humira plus MTX group. Malignancies occurred in seven patients (2.2%) in the ORENCIA plus MTX group and seven patients (2.1%) in the Humira plus MTX group.

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, swelling and fatigue. 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.

Important Safety Information

Concomitant Use with TNF antagonists: Concurrent therapy with ORENCIA and a biologic DMARD 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: Less than 1% of adult patients treated with ORENCIA experienced hypersensitivity reactions, including some cases of anaphylaxis or anaphylactoid reactions. Other events potentially associated with drug hypersensitivity, such as hypotension, urticaria, and dyspnea, each occurred in less than 0.9% of patients treated with ORENCIA® (abatacept) and generally occurred within 24 hours of infusion. There was 1 case of a hypersensitivity reaction with ORENCIA in JIA clinical trials (0.5%; n =190). Appropriate medical support measures for treating hypersensitivity reactions should be available for immediate use in the event of a reaction.

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 as it 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 (abatacept) 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 pyrroloquinolinequinone (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 administration does not contain maltose; therefore, patients do not need to alter their glucose monitoring.

Pregnant and Nursing Mothers: ORENCIA® (abatacept) 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 vs. 1.9% placebo) and malignancies (1.3% ORENCIA vs. 1.1% placebo). In general, adverse events in pediatric and adolescent patients were similar in frequency and type to those seen in adult patients.

Malignancies: The overall frequency of malignancies was similar between adult patients treated with ORENCIA (abatacept) 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.

For US Full Prescribing Information, visit http://packageinserts.bms.com/pi/pi_orencia.pdf.

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

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

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 product development. 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 the clinical trials of these compounds will support regulatory filings, or that the compounds will receive regulatory approvals or, if approved, that they will become commercially successful products. 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, 2012, 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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