Bristol-Myers Squibb Announces Availability of FDA-Approved ORENCIA® (abatacept) ClickJect™, a Self-Administered Subcutaneous Autoinjector, for Adults with Moderate to Severe Rheumatoid Arthritis

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ORENCIA is the only biologic treatment for moderate to severe rheumatoid arthritis that is approved in three administration options - IV infusion, prefilled syringe, and autoinjector 1-10

New ORENCIA ClickJect Autoinjector offers accurate dose self-injection with push button operation, and confirmation that the full dose has been injected 11

Patients with moderate to severe RA who tested the ClickJect Autoinjector found the design comfortable and easy-to-use

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today the commercial launch of the ORENCIA ClickJect™ Autoinjector, a new self-administered autoinjector for adults with moderate to severe rheumatoid arthritis (RA). The ORENCIA ClickJect delivers 125 mg of subcutaneous (SC) ORENCIA with push button operation and injection confirmation, which may reduce the possibility of user errors. The ORENCIA ClickJect has an ergonomic design and non-slip grip that may allow for control by dexterity-compromised patients. 11 ORENCIA is the only RA biologic that offers three administration options: IV infusion, prefilled syringe and Autoinjector. 1-10 ORENCIA is a prescription medicine 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 should not be administered concomitantly with tumor necrosis factor (TNF) antagonists, and is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

"Today’s launch of the ORENCIA ClickJect is an example of our continued commitment to offering patients with moderate to severe rheumatoid arthritis a treatment option that may be appropriate for them, now available as an autoinjector,” said Chris Boerner, Head of U.S. Commercial, Bristol-Myers Squibb. “This approval offers more options for healthcare providers and members of the arthritis community to consider when selecting the optimal treatment and administration option for each individual.”

In a summative study, patients (n=48) evaluated the ORENCIA ClickJect Autoinjector usability and acceptability based on key attributes, including comfort (patients, P=0.0157), control (patients, P=0.0002), ease of use (patients, P=0.0210) and confidence of dose (patients, P=0.896). The mean scores for the device across criteria ranged from 6.4-6.9 with the patient group, where user experience was measured using a 7-point scale (1=very unacceptable, 4=neutral, 7=very acceptable). Studies were conducted by an independent company and participants were informed that a new RA autoinjector was being tested but were blinded to the intended drug and sponsor identity. 11

For patients with early, rapidly progressing moderate to severe RA, treatment with ORENCIA may be an appropriate option. In a 12-month, multinational, double-blind, randomized, Phase IIIIB study of methotrexate (MTX)-naïve patients with early, rapidly progressing RA, ORENCIA IV + MTX demonstrated significant efficacy vs MTX alone for those with moderate to severe RA. The study, AGREE, met its co-primary endpoints as defined by proportion of patients achieving DAS28-CRP < 2.6 at 1 year (41% vs 23%, P<0.001) and inhibition of radiographic progression at 1 year (mean change in total symptoms scores: 0.6 vs 1.1, P=0.04). Headache, upper respiratory tract infection, nasopharyngitis, and nausea were the most commonly reported adverse events occurring at a rate of ≥ 10% in patients taking ORENCIA in the adult RA clinical...
“Rheumatoid arthritis often affects joints in the hand and impairs dexterity.” Through the new ORENCIA Clickject, we are able to offer the proven benefits of ORENCIA in an accurate dose self-injection and provide an additional option for healthcare providers when selecting treatment options for their patients,” said Sheila Kelly, M.D., U.S. ORENCIA Medical Lead, Bristol-Myers Squibb.

The new ORENCIA Clickject comes with push button operation and step-by-step instructions to help the injection process for patients. The Autoinjector’s sturdy, lightweight design may allow patients with RA to firmly hold, operate and control the device. It automatically delivers the full dose of ORENCIA with one push of a button and the user holding for fifteen seconds. Also, the Clickject Autoinjector’s large viewing window and blue indicator help confirm the full dose of ORENCIA has been injected. The Clickject’s Autoinjector’s transparent tip automatically locks and covers the needle after injection to help prevent accidental needle sticks.

Physicians and patients interested in receiving more information about the ORENCIA Clickject should visit www.ORENCIAHCP.com or call 1-800-ORENCIA.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a systemic, chronic, autoimmune disease characterized by inflammation in the lining of the 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)

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 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 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 JA 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-PQO). 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 JA 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.

Please see Full Prescribing Information at http://packageinserts.bms.com/pi/pi_orencia.pdf.

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 for patients suffering from immune-mediated disease. As we learn more about the immune system in diseases with substantial unmet needs, the potential for new therapies that modulate 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, 2015 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.

References:

1. Enbrel Prescribing Information. U.S. Food and Drug Administration. 2015. Available at:


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