Bristol-Myers Squibb Announces Availability of New ORENCIA® (abatacept) Subcutaneous Administration Option for Patients 2 Years of Age and Older with Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis (JIA)

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New prefilled syringe option can be administered at home

PRINCETON, N.J.--(BUSINESS WIRE)-- Bristol-Myers Squibb Company (NYSE:BMY) announced today the availability of a new FDA-approved subcutaneous (SC) ORENCIA administration option for use in patients 2 years of age and older with moderately to severely active polyarticular Juvenile Idiopathic Arthritis (JIA).\(^1\) The new prefilled syringe offers physicians, patients, and caregivers of these patients the option of ORENCIA treatment that can be administered at home.\(^1\) In 2008, ORENCIA IV was the first FDA-approved IV biologic for use in patients 6 years of age and older with moderately to severely active polyarticular JIA.

"The data supporting this new FDA approved prefilled syringe provide a scientific basis for the dosing, efficacy and safety of subcutaneous abatacept in JIA and add to the growing body of clinical evidence for patients 2 years of age and older living with this difficult and immune disease," said Daniel J. Lovell, M.D., M.P.H., Joseph E. Levinson Endowed Chair of Pediatric Rheumatology and Professor of Pediatrics, University of Cincinnati Medical Center. "Importantly, subcutaneous abatacept also provides physicians a new administration option to offer their patients."

JIA is the most common type of arthritis in children and a condition that makes it difficult to do everyday things, and may eventually result in disability.\(^2\) ORENCIA SC is a prescription medicine that is indicated for reducing signs and symptoms in patients 2 years of age and older with moderately to severely active JIA.\(^1\) ORENCIA may be used as monotherapy or concomitantly with methotrexate (MTX).\(^1\) ORENCIA should not be administered concomitantly with other biologic RA therapy, such as anakinra.\(^1\)

ORENCIA SC should be initiated without an IV loading dose and administered once-weekly using weight-tiered dosing: 50 mg/0.4 mL syringe (for patients 10 to <25 kg), 87.5 mg/0.7 mL syringe (for patients 25 to <50 kg) and 125 mg/mL syringe (for patients ≥50 kg).\(^1\) Dosage is to be determined by a physician.\(^1\) Patients or caregivers should receive training on the right way to prepare and inject ORENCIA.\(^1\)

It is not known if ORENCIA SC is safe and effective in children under 2 years of age.\(^1\) Intravenous dosing has not been studied in patients younger than 6 years of age.\(^1\) The safety and efficacy of ORENCIA ClickJect™ Autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

In Study JIA-2, an open-label, phase 3 study with a 4-month short-term period (n=205) and a 20 month open-label extension period, the primary objective was evaluation of PK in order to support the extrapolation of efficacy based on exposure to ORENCIA supported by descriptive efficacy. Pharmacokinetics, safety and efficacy of SC ORENCIA were assessed in patients ages 2 to 17 years with JIA and an inadequate response to at least one nonbiologic or biologic DMARD. At study entry, 80% of patients were receiving methotrexate and remained on a stable dose of methotrexate.\(^1\) JIA ACR 30, 50, and 70 response rates at 4 months were 81%, 71% and 53%, respectively and were observed to be consistent with the results from the IV study, JIA-1.\(^3\)

In general, the adverse events observed in pediatric patients with Juvenile Idiopathic Arthritis were similar in frequency and type to those seen in adult patients.\(^1\)

In the intravenous Study JIA-1, the overall frequency of adverse events in the 4-month, lead-in, open-label period of the study was 70%; infections occurred at a frequency of 36%. The most common infections were upper respiratory tract infection and nasopharyngitis. The infections resolved without sequelae, and the types of infections were consistent with those commonly seen in outpatient pediatric populations. Other events that occurred at a prevalence of at least 5% were headache, nausea, diarrhea, cough, pyrexia, and abdominal pain. A total of 6 serious adverse events (acute lymphocytic
leukemia, ovarian cyst, varicella infection, disease flare [2], and joint wear) were reported during the initial 4 months of treatment with ORENCIA IV. One case of a hypersensitivity reaction (0.5%) was reported. During Periods A, B, and C of Study JIA-1, acute infusion-related reactions occurred at a frequency of 4%, 2%, and 3%, respectively, and were consistent with the types of events reported in adults. Upon continued treatment in the open-label extension period, the types of adverse events were similar in frequency and type to those seen in adult patients, except for a single patient diagnosed with multiple sclerosis while on open-label treatment.1

The safety experience and immunogenicity for ORENCIA administered subcutaneously in Study JIA-2 were consistent with the intravenous Study JIA-1.1 There were no reported cases of hypersensitivity reactions and local injection-site reactions occurred at a frequency of 4.4%.1

“Juvenile Idiopathic Arthritis can cause pain, stiffness and swelling that may make it difficult for children to do everyday things like playing with friends or riding a bike.2 Understandably, the condition can impact the entire family,” said Brian J. Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb. “We’re proud to be able to provide a new subcutaneous administration option1 for ORENCIA, a proven choice for patients with JIA, as part of our commitment to advancing immunoscience research to address unmet needs and supporting JIA patients and their families.”

Physicians, patients, and parents interested in learning more about ORENCIA for moderate to severe JIA should visit www.ORENCIA.com or call 1-800-ORENCIA.

About Juvenile Idiopathic Arthritis

Affecting more than 50,000 children in the United States,5 Juvenile Idiopathic Arthritis (JIA) is the most common type of arthritis in children.2 Potentially involving one or many joints, JIA may cause damage that makes it difficult to do everyday things and may eventually result in disability.2

Indication and Important Safety Information for ORENCIA® (abatacept)

Indication and Usage

Adult Rheumatoid Arthritis (RA): 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 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 patients 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, adults 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 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 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 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.

**Please click here to see the Full Prescribing Information.**

ORENCIA® (abatacept) is a registered trademark of Bristol-Myers Squibb Company. ClickJet™ is a 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 transformational medicines for patients suffering from immune-mediated disease. As we learn more about the immune system in diseases with substantial unmet medical 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, 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.

**References**

1. ORENCIA® Prescribing Information. Bristol-Myers Squibb Company, Princeton, NJ.
Ticker: BMY
Exchange: NYSE

Contact:
Bristol-Myers Squibb Company
Media:
Erin McMaster, 609-955-2253
erin.mcmaster@bms.com
or
Investors:
Bill Szablewski, 609-252-5894
william.szablewski@bms.com

Ticker Slug:
Ticker: BMY
Exchange: NYSE