Data Demonstrate ORENCIA(R) (abatacept) Improves Health-Related Quality of Life, Pain and Sleep Quality in Children With Juvenile Idiopathic Arthritis

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SAN FRANCISCO--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced at the American College of Rheumatology (ACR) Annual Scientific Meeting in San Francisco results from a 10-month study which showed that ORENCIA® (abatacept), compared to placebo, significantly improved multiple aspects of health-related quality of life (HRQoL): physical and psychosocial well being, pain and sleep quality in juvenile idiopathic arthritis (JIA) patients between the ages 6 and 17 years. These improvements with ORENCIA were maintained throughout the 10-month study period, during which the first four months included an open-label lead-in period and the last six months comprised a randomized, double-blind, placebo-controlled study.

These results were part of a study looking at the safety and efficacy of ORENCIA in children with JIA who had failed on previous treatments such as methotrexate (MTX) or biologics.1 Data from this study was used to obtain U.S. Food and Drug Administration approval of ORENCIA on April 8, 2008, for reducing the signs and symptoms in children and adolescents 6 years of age and older with moderate-to-severe polyarticular JIA. In children and adolescents, ORENCIA may be used alone or with MTX.2

"Health-related quality of life, or HRQoL, in children with JIA can be significantly impaired due to pain, joint damage and inflammation," said the study’s lead investigator, Daniel Lovell, M.D., M.P.H., director, Division of Rheumatology, Cincinnati Children’s Hospital Medical Center. "Therefore, successful treatment of JIA should positively impact patient-centered outcomes in HRQoL, daily functioning and psychosocial well being."

Study Design and Findings

In this 10-month, two-phase study, 190 children with JIA between the ages of 6 and 17 years were enrolled. In the first phase of the study (Period A), which was an open-label lead-in period, all patients were treated with ORENCIA 10 mg/kg intravenously at Day 1, 15, 29, and approximately every 28 days thereafter for four months. In Period B, patients who completed Period A and achieved an American College of Rheumatology Pediatric (ACR Pedi) 30 percent response—defined as 30 percent or more improvement in at least three of the six JIA core set variables and not more than one JIA core variable showing 30 percent or more worsening2—were then randomized to a double-blind withdrawal phase with ORENCIA® (abatacept) or placebo for up to six months (ORENCIA n=60; placebo n=62).

There were three validated measures in this study used to assess HRQoL. The first was the Child Health Questionnaire (CHQ), which contains 15 health domains covering a child’s physical and psychosocial well being and the impact of JIA on parents and family.3,4 The second was sleep quality, as measured by the Children’s Sleep Habits Questionnaire (CSHQ), which has eight domains that measure the most common sleep problems in children and adolescents: bedtime resistance, sleep onset delay, sleep duration, sleep anxiety, night wakeings, parasomnias, sleep disordered breathing and daytime sleepiness.5 The third measure was pain, assessed by a Visual Analog Scale (VAS) Score of 0 to 100 mm.6 The VAS Score for pain is a global quality-of-life indicator in which the patient identifies along a continuum the amount of pain they are feeling.6 For these measures, mean change from baseline in each period was calculated and compared between the treatment groups in Period B and the change over time.

At the conclusion of Period A (four months), treatment with ORENCIA demonstrated significant improvements on all patient reported measures. Improvements in CHQ scores were significant in 14 out of 15 health domains measured (as measured by 95 percent confidence intervals). The greatest CHQ improvements were seen in the physical domain, which consists of physical functioning, bodily pain, role-physical and general health. With ORENCIA, pain was significantly reduced by Day 15 of Period A (-5.9 points; as measured by 95 percent confidence intervals) and was further reduced by the end of the period (-18.7 points; as measured by 95 percent confidence intervals). On the CSHQ, the sleep problem index decreased significantly by 1.86 points (p-value less than 0.05).

At the end of Period B, most ORENCIA patients maintained or continued these HRQoL improvements in 10 of the 15 CHQ health domains, while placebo patients generally experienced declining HRQoL (in 13 of 15 CHQ health domains), increased pain (+8.4 points; as measured by 95 percent confidence intervals) and sleep problems (+1.2 points; as measured by 95 percent confidence intervals).

Additional data from this study will also be presented at the ACR Annual Scientific Meeting by Tracy Li, Ph.D, director, Global Health Outcomes, Bristol-Myers Squibb, on Wednesday, October 29, at 8 a.m. (Pacific Time). Dr. Li’s presentation, which will look at the real-life impact of ORENCIA® (abatacept) on JIA patients and their parents, is entitled “Reduction in Missed
School Days and Improvements in Parent Activity Participation in Children with Juvenile Idiopathic Arthritis Treated with Abatacept."

About ORENCIA® (abatacept)
ORENCIA is a prescription medicine that is used to treat adults with moderate to severe RA including those who have not been helped enough by other medicines for RA. ORENCIA may prevent further damage to bones and joints, and may help the individual’s ability to perform daily activities. In adults, ORENCIA may be used alone or with disease-modifying anti-rheumatic drugs (DMARDs) other than tumor necrosis factor (TNF) antagonists.

ORENCIA also reduces signs and symptoms in children and adolescents six years of age and older with moderate to severe polyarticular JIA. In children and adolescents, ORENCIA may be used alone or with MTX.

ORENCIA should not be used with TNF antagonists and is not recommended for use with other biologic RA therapy, such as anakinra.

About Juvenile Idiopathic Arthritis (JIA)
JIA – also commonly known as Juvenile Rheumatoid Arthritis (JRA) – is the most common chronic rheumatic disease in children, and it is an important cause of short-term and long-term disability. It is an autoimmune disease that causes chronic pain, stiffness and swelling of the joints, which may ultimately lead to joint damage and deformities. The disease usually begins before the age of 16. Juvenile arthritis may affect up to one in every 1,000 children in the United States. ORENCIA is indicated in pediatric patients ages six years and older with moderately to severely active polyarticular JIA. ORENCIA may be used as monotherapy or concomitantly with MTX in pediatric patients. ORENCIA should not be used with TNF antagonists, and is not recommended for use with other biologic RA therapy, such as anakinra.

Important Safety Information About ORENCIA® (abatacept)
Before receiving treatment with ORENCIA, a lyophilized powder for intravenous infusion, individuals should tell their doctor about all their medical conditions, including if they have any kind of infection even if it is small (such as an open cut or sore) or an infection that is in the whole body (such as the flu) or have an infection that will not go away or a history of infections that keep coming back. People should tell their doctor if they have had tuberculosis (TB), a positive skin test for TB, or recent close contact with someone who has had TB. If symptoms of TB occur (a dry cough that doesn’t go away, weight loss, fever, night sweats), they should call their doctor right away. Before starting treatment with ORENCIA, a doctor may examine the person for TB or perform a skin test.

Individuals who have or have had viral hepatitis should tell their doctor. The doctor may want to examine them for hepatitis before using ORENCIA. People should inform their doctor if they have a history of chronic obstructive pulmonary (lung) disease (COPD). In addition, individuals should let their doctor know if they are scheduled to have surgery, or recently received a vaccination or are scheduled for any vaccination.

People should also let their doctor know if they are allergic to any of the following ingredients in ORENCIA: abatacept, maltose, monobasic sodium phosphate, or sodium chloride for administration. People who have diabetes and use a blood glucose monitor to check sugar levels should tell their doctor. The infusion of ORENCIA contains maltose, a sugar that can give falsely high blood glucose readings with some monitors on the day of the infusion. The doctor may tell them to use a different way to monitor their blood sugar levels.

Women who are pregnant, planning to become pregnant, or are thinking about becoming pregnant should tell their doctor. It is not known if ORENCIA can harm your unborn baby. Women who are breast feeding should also inform their doctor. They will need to decide to either breast-feed or receive treatment with ORENCIA, but not both.

People taking ORENCIA should notify their doctor if they are taking any other kinds of medicine, including prescription and nonprescription medicines, vitamins, and herbal supplements. It is also important for individuals to tell their doctor if they are taking other biologic medicines to treat RA or JIA such as: Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Kineret® (anakinra) or Rituxan® (rituximab). You may have a higher chance of getting a serious infection if you take ORENCIA® (abatacept) with other biologic medicines.

Possible Side Effects of ORENCIA® (abatacept)
ORENCIA can cause serious side effects including serious infections. People receiving ORENCIA have a higher chance of getting infections including pneumonia, and other infections caused by viruses, bacteria, or fungi. Individuals should call their doctor immediately if they 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 can happen on the day of treatment or the day after receiving ORENCIA. People should tell their doctor or get emergency medical help right away if they have hives, swollen face, eyelids, lips, tongue, throat, or trouble breathing.

Certain kinds of cancer (malignancies) have been reported in people receiving ORENCIA. It is not known if ORENCIA increases the chance of getting certain kinds of cancer.

Individuals should not receive ORENCIA with certain types of vaccines. ORENCIA may cause some vaccinations to be less effective.

Respiratory problems in people with COPD. Individuals may get certain respiratory problems more often if they receive ORENCIA and have COPD, including: worsened COPD, pneumonia, cough, or trouble breathing.

The more common side effects with ORENCIA in both adults and children are headache, upper respiratory tract infection,
sore throat, and nausea. Other side effects in children may include diarrhea, cough, fever, and abdominal pain.

Please see accompanying Full Prescribing Information, or visit www.ORENCIA.com or www.bms.com.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information visit www.bms.com.

References


2 ORENCIA® (abatacept) [prescribing information], Princeton, NJ: Bristol-Myers Squibb; April 2008.


9 Zeginni E. Association of HLA-DRB1*13 with susceptibility to uveitis in juvenile idiopathic arthritis in two independent data sets. Rheumatology. 2006;45:972-974.


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