

13.06.2007 - 10:00 Uhr

ORENCIA® (Abatacept) Demonstrates Continued Improvement in Clinical Response Through 12 Months

Barcelona (ots) -

New Results Represent Additional Data From a Study Showing Superior Efficacy of ORENCIA or Infliximab Compared to Placebo at Six Months

Bristol-Myers Squibb Company (NYSE: BMY) today announced additional study results providing evidence of the efficacy and durability of response of ORENCIA(R) (abatacept) through 12 months in adults with moderate to severe rheumatoid arthritis (RA) who have had an inadequate response to methotrexate (MTX).

This study originally evaluated the efficacy, safety and tolerability of ORENCIA® plus MTX, infliximab, an anti-TNF inhibitor, plus MTX, and placebo plus MTX at 6 months. The study previously showed that ORENCIA(R) or infliximab had superior efficacy compared to placebo at six months. (1)

ORENCIA®, in combination with MTX - a standard therapy for RA patients - is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have had an insufficient response or intolerance to other disease-modifying anti-rheumatic drugs including at least one anti-tumour necrosis factor (TNF) inhibitor. A reduction in the progression of joint damage and improvement of physical function has been demonstrated with combination treatment with ORENCIA® and MTX.

In new results reported today at the 8th Annual European Congress of Rheumatology (EULAR), data showed at 12 months ORENCIA® demonstrated a durable response as per assessments including DAS28-derived criteria, EULAR response and Health Assessment Questionnaire - Disability Index (HAQ-DI results).

"As rheumatoid arthritis is a chronic condition for many patients, we need to understand the potential of treatments over time," said Maxime Dougados, M.D., Professor of Rheumatology, Universite Rene Descartes, Paris. "The results of this study suggest continued improvement for Orenzia-treated patients. This is important as we determine how to provide care to patients who do not adequately respond to currently available therapies."

The study randomized participants with moderate to severe RA who have had an inadequate response to MTX and no prior anti-TNF therapy. Patients received ORENCIA(R) (n=156), infliximab (active control, n=165) or placebo (n=110). All groups continued on MTX through 12 months. The study was not designed to directly compare the active treatment arms.

The primary endpoint was mean reduction in disease activity score (DAS28) in the group receiving ORENCIA vs. placebo at six months. Secondary objectives included mean reduction in DAS28 with infliximab vs. placebo at six months, mean reduction in DAS28 with ORENCIA® and infliximab at one year, physical function as measured by the Health Assessment Questionnaire (HAQ), and the proportion of patients treated with ORENCIA® or infliximab at 12 months who demonstrated a

good, moderate or no response according to the EULAR criteria. DAS28 is an index of disease activity and is calculated by assessing the number of swollen and tender joints, measuring a laboratory parameter and evaluating a patient's global health. Thresholds have been developed for low disease activity (DAS28<3.2) and remission (DAS28<2.6). This score is used in the EULAR definition of good, moderate and no response. Good response requires two components - improvement relative to the past (a decrease in DAS28 by more than 1.2) and improvement to a level of low activity (DAS28 is less than 3.2).

Six Month Study Results (Efficacy)

Therapy	DAS28<3.2 Response	DAS28<2.6 Response	Good EULAR Responders	Moderate HAQ Responders
ORENCIA®	20.7%	11.3%	20.0%	56.7% 61.5% (n=156)
Infliximab	25.6%	12.8%	22.9%	42.7% 58.8% (n=165)
Placebo	10.8%	2.9%	10.8%	44.1% 40.9% (n=102)

Twelve Month Study Results (Efficacy)

Therapy	DAS28<3.2 Response	DAS28<2.6 Response	Good EULAR Responders	Moderate HAQ Responders
ORENCIA®	35.3%	18.7%	32.0%	40.7% 57.7%(n=156)
Infliximab	22.4%	12.2%	18.5%	45.2% 52.7%(n=165)

The study also evaluated the safety profile of treatment at 6 months and 12 months. Through 12 months, ORENCIA® had fewer serious infections, acute infusional events and discontinuations due to adverse events than infliximab.

Six Month Study Results (Safety)

Therapy	Adverse Events (AE)	Serious AE	Acute Infusional AE
ORENCIA®	82.7%	5.1%	5.1% (n=156)
Infliximab	84.8%	11.5%	18.2% (n=165)
Placebo	83.6%	11.8%	10.0% (n=102)

Twelve Month Study Results (Safety)

Therapy	Adverse Events (AE)	Serious AE due to AE	Discontinuation due to Serious AE	Discontinuation as Serious AE	Infections reported of acute infusional AE	Frequency
ORENCIA®	89.1%	9.6%	3.2%	2.6%	1.9%	7.1% (n=156)
Infliximab	93.3%	18.2%	7.3%	3.6%	8.5%	24.8%(n=165)

About Orencia

ORENCIA® is a novel medicine as the first and only selective co-stimulation modulator of T-cell activation. ORENCIA® is the first biologic discovered and developed in Bristol-Myers Squibb research centers and was approved in May 2007 by the European Commission.

Medicinal products, including ORENCIA®, which affect the immune system, may affect host defenses against infections and malignancies. Serious infections at least possibly related to treatment were reported in 1.8% of patients with ORENCIA® and in 1.0% of patients not treated by ORENCIA® (receiving placebo). There is a need to evaluate and monitor the patients regarding the risk of infection prior to and during treatment. In the placebo-controlled clinical

trials, the frequency of malignancies with ORENCIA(R) was 1.4% and with placebo 1.1%. These rates are similar to that observed in the general rheumatoid arthritis population.(2)

ORENCIA® is contraindicated in patients with severe and uncontrolled infections such as sepsis and opportunistic infections and in patients with hypersensitivity to the active substance or to any of the excipients. Allergic reactions have been reported uncommonly with ORENCIA® in clinical trials, where patients were not required to be pretreated to prevent allergic reactions. In the case of any serious allergic/anaphylactic reaction, ORENCIA® should be discontinued.

About Rheumatoid Arthritis

Rheumatoid arthritis 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 function as a result of affected joints losing their shape and alignment. RA may affect up to 4.5 million people in the European Union.(3),(4)

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.

ORENCIA® (abatacept) is a trademark of Bristol-Myers Squibb Company.

For information for ORENCIA®, please consult the Summary of Product Characteristics.

(1) Schiff et al. ACR 2006.

(2) Simon T et al. EULAR 2006.

(3) http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-07-041/EN/KS-SF-07-041-EN.PDF accessed 25-04-07.

(4) http://ec.europa.eu/health/ph_information/dissemination/diseases/musculo_en.htm accessed 25-04-07.

Contact:

Brian Henry
Bristol-Myers Squibb
Office: +33-1-58-83-69-38
Mobile: +33-6-75-09-08-99
E-Mail: brian.henry@bms.com

Diese Meldung kann unter <https://www.presseportal.ch/fr/pm/100016013/100536044> abgerufen werden.