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European Commission Grants Approval for ORENCIA(R) (abatacept) for Treatment of Rheumatoid Arthritis

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- Innovative, First-in-Class Medicine Provides New Option for Europeans With Debilitating Disease

Bristol-Myers Squibb (NYSE: BMY) announced today the European Commission has granted an approval for ORENCIA(R) (abatacept) for the treatment of rheumatoid arthritis (RA), a disease that may affect up to 4.5 million people in the European Union (1),(2).

ORENCIA(R) is a novel medicine as the first and only selective co-stimulation modulator of Tcell activation. ORENCIA(R) is the first biologic discovered and developed in Bristol-Myers Squibb research centers and will be available in several countries in the European Union as of June 2007.

ORENCIA(R), in combination with methotrexate - 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(R) and methotrexate.

"Orencia is the third new medicine we have launched in Europe in the past 11 months, demonstrating Bristol-Myers Squibb's commitment to bringing innovative medicines to patients with unmet medical needs, " said Beatrice Cazala, President, Europe, Middle East and Africa for Bristol-Myers Squibb. "Orencia is the next generation biologic and offers physicians a new way of treating patients with rheumatoid arthritis."

Autoimmune diseases such as RA are characterized by an overactive immune system that turns its attack on itself instead of invading microbes. This immune system attack causes inflammation, pain, stiffness and swelling of the joints and can eventually lead to cartilage breakdown, bone loss and weakness of the joints. The costs of inadequately controlled rheumatoid arthritis, which include lost productivity and earnings of patients and caregivers, represent a substantial burden, particularly in working-age patients(3).

T-cells are immune cells thought to play a major role in the development of rheumatoid arthritis(4). Full activation of T-cells requires two signals: a main one and a second, costimulatory signal. ORENCIA(R) interrupts the inflammatory process associated with rheumatoid arthritis by selectively modulating one of the necessary costimulatory activation signals.

"Rheumatoid arthritis patients live with pain, discomfort and disfigurement, believing there is little that can be done," said Paul Emery, M.D., Arc Professor of Rheumatology; Clinical Director,

Leeds Teaching Hospitals Trust, Academic Unit of Musculoskeletal Disease, Department of Rheumatology, Leeds General Infirmary, Leeds, United Kingdom. "The response we see with Orencia can lead to more

active days for rheumatoid arthritis patients, part of our goal to improve all clinical outcomes, including patient well-being."

The efficacy and safety profile of ORENCIA(R) have been studied through a clinical trial program that included more than 2,600 patients across the placebo-controlled and open-label extension periods of the clinical trials. ORENCIA(R) in combination with methotrexate demonstrated significant and sustained improvement of the signs and symptoms of rheumatoid arthritis patients who failed or were inadequate responders to currently-available therapies such as methotrexate or anti-TNF inhibitors. ORENCIA(R) in combination with methotrexate also demonstrated significant and clinically meaningful improvement in physical function that was maintained up to 48 months

With regards to disease-modifying effect assessed radiographically, ORENCIA(R) in combination with methotrexate reduced the rate of progression of structural joint damage compared to placebo and methotrexate after 12 months and further reduction in X-ray progression was seen through two years.

Medicinal products, including ORENCIA(R), which affect the immune system may affect host defences against infections and malignancies. Serious infections at least possibly related to treatment were reported in 1.8% of patients with ORENCIA(R) and in 1.0% of patients not treated by ORENCIA(R) (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(5)

ORENCIA(R) 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(R) 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(R) should be discontinued.

ORENCIA(R) is initially administered in a 30-minute intravenous injection on the first, 15th and 30th day of treatment, then once every four weeks thereafter. ORENCIA(R) is approximately dosed at 10 milligrams per each kilogram of body weight and without need for premedication. Administration times of other currently available intravenous treatments for rheumatoid arthritis can be two hours or more per treatment. Treatment with ORENCIA(R) should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

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

Refer to the ORENCIA(R) Summary of Product Characteristics for further information or contact Brian Henry, Bristol-Myers Squibb Corporate and Business Communications, on +33-1-58-83-69-38.

(1)
http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-07-041/EN/KS-SF-07-041-EN.PDF accessed 25-04-07

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

(3) Pugner KM, Scott DI, Holmes JW, et al. The costs of rheumatoid arthritis: an international long-term view. Sem Arthritis Rheum. 2000;29:305-20.

(4) Choy EH, Panayi GS. "Cytokine Pathways and Joint Inflammation in Rheumatoid Arthritis." N Engl J Med. 2001;344:907-916. In health-related quality of life, clinically and statistically significant improvement was observed in the ORENCIA group as compared with the placebo group in all individual and composite physical and mental health aspects.

(5) Simon T, poster presentation at EULAR 2006

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