If approved for the new indication,ORENÇIA would be the first biologic therapy with an EU indication specifically applicable to the treatment of MTX-naive RA patients with highly active and progressive disease.

Would mark the first time that MRI assessment of structural and inflammatory measures of disease severity are cited in SmPC to support an RA indication.

The positive opinion was informed by data from two Phase 3 studies: In a 12 month, multinational, double-blind, randomized, Phase 3B study of MTX-naive patients with early, rapidly progressing RA, ORENÇIA IV + MTX demonstrated significant efficacy vs MTX alone for those with moderate to severe RA. The study, AGREE (Abatacept study to Gauge Remission and joint damage progression in MTX-naive patients with Early Erosive RA), met its co-primary endpoints as defined by the 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 Sharp score: 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 ORENÇIA in the adult RA clinical studies.
ORENCIA undertook [3 of 37 patients (8%) and pneumonia [1 of 37 patients with ORENCIA developed a serious adverse event 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.

The second Phase 3 data is from the AVERT study, which compared ORENCIA 125 mg subcutaneous + MTX combination therapy, ORENCIA 125 mg subcutaneous monotherapy, and MTX monotherapy in induction of DAS28-defined remission following 12 months of treatment in 351 adult patients with moderate to severe active, early RA (mean DAS28 CRP of 5.4; mean symptom duration less than 6.7 months) who had not been treated with MTX or other DMARDS earlier (MTX-naïve).² Patients also had poor prognostic factors for rapidly progressive disease (positive for anti-CCP antibodies, and/or RF+, presence of baseline joint erosions).³ The co-primary endpoints compared the proportion of patients with DAS28-defined remission (DAS28 CRP <2.6) at month 12 and both months 12 and 18 for ORENCIA + MTX versus MTX alone.³ At 12 months, significantly more patients on ORENCIA combination therapy achieved DAS28-defined remission than MTX alone (60.9%, ORENCIA + MTX; 45.2%, MTX alone).³ Similar results at 12 months were seen with other measures of efficacy including Boolean remission (37.0%, ORENCIA + MTX; 22.4%, MTX alone), CDAI remission (42%, ORENCIA + MTX; 27.6% MTX alone), and SDAI remission (42%, ORENCIA + MTX; 25% MTX alone).³ The CHMP’s positive opinion is based on clinical response to ORENCIA as well as X-Ray and MRI assessment of structural and inflammatory measures of disease severity.

“The CHMP’s recommendation for ORENCIA is a milestone built on Bristol-Myers Squibb’s commitment to advancing the science of earlier identification of patients with progressive RA prior to their suffering debilitating joint damage,” said Brian J. Gavin, Vice President, ORENCIA Development Lead at Bristol-Myers Squibb. “The potential to provide a biologic treatment option in the EU for MTX-naïve RA patients who have highly active and progressive disease is clinically significant, and we look forward to the European Commission decision.”

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) 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 in the joints.³ RA causes decreased range of motion and function in the joints.³ The condition is three times more common in women than in men.³

U.S. 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 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, 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 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.
Bristol-Myers Squibb Company

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

Language:
English

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