Generic Name:
Baricitinib
Trade Name:
Olumiant
Company:
Eli Lilly, Incyte
Notes:

Eli Lilly and Incyte announced FDA approval of a 2-mg dose of baricitinib, a once-daily oral medication to treat moderately to severely active rheumatoid arthritis (RA) in adults who have had an inadequate response to one or more tumor necrosis factor (TNF)?inhibitor therapies.

Use of baricitinib in combination with other Janus kinase inhibitors or biologic disease?modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. Baricitinib may be used as monotherapy or in combination with methotrexate or other nonbiologic DMARDs.

Approval was based on a clinical trial program that included the RA-BEACON study, a randomized, double-blind, placebo-controlled study in which patients were randomly assigned to receive baricitinib 2 mg, baricitinib 4 mg or placebo, in addition to conventional DMARDs they were currently using. The study included 527 patients who had an inadequate response or intolerance to one or more TNF-inhibitor therapies. Patients could have had prior therapy with other bDMARDs.

The study results showed significantly higher ACR20 response rates and improvement in all individual ACR20 component scores at week 12 with use of baricitinib. Patients treated with baricitinib had significantly higher rates of ACR20 response versus patients treated with placebo at week 12 (49% of baricitinib-treated patients versus 27% of placebo-treated patients).

Baricitinib also demonstrated early symptom relief, with ACR20 responses seen as early as week 1. Patients reported significant improvements in physical function according to the Health Assessment Questionnaire Disability Index (HAQ-DI) (recording an average score of 1.71 before treatment and 1.31 at week 12) compared with placebo-treated patients (who recorded an average score of 1.78 before treatment and 1.59 at week 12).

Baricitinib is approved with a boxed warning for the risk of serious infections, malignancies, and thrombosis. Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving baricitinib

Lymphoma and other malignancies have been observed in patients treated with baricitinib as well. In addition, thrombosis?including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal?have occurred in some patients.

Other warnings and precautions include gastrointestinal perforations, laboratory abnormalities

(including neutropenia, lymphopenia, anemia, liver enzyme elevations, and lipid elevations), and a warning against use of live vaccines with baricitinib.

The most common adverse events in clinical trials included upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

As part of the approval, the companies have agreed to conduct a randomized, controlled clinical trial to evaluate the long-term safety of baricitinib in patients with RA.

Medication Monitor Categories:
New Drug Approvals
