Generic Name:
Erdafitinib
Trade Name:
Balversa
Company:
Janssen
Notes:

FDA granted accelerated approval to erdafitinib for treatment of adult patients with locally advanced or metastatic bladder cancer that has a FGFR3 or FGFR2 genetic alteration, and that has progressed during or following prior platinum-containing chemotherapy. An FDA-approved companion diagnostic device must be used to select patients for treatment.

Bladder cancer is the sixth most common cancer in the United States. Transitional cell carcinoma, also called urothelial carcinoma, is the most common type. Bladder cancers are associated with genetic mutations that are present in the patient's bladder or entire urothelium. Fibroblast growth factor (FGFR) alterations are present in approximately one in five patients with recurrent and refractory bladder cancer.

Efficacy of erdafitinib was studied in a clinical trial that included 87 patients with locally advanced or metastatic bladder cancer, with FGFR3 or FGFR2 genetic alterations, that had progressed following treatment with chemotherapy. The overall response rate in these patients was 32.2%, with 2.3% having a complete response and almost 30% having a partial response. The response lasted for an average of approximately 5.5 months.

About a quarter of patients in the study were previously treated with anti PD-L1/PD-1 therapy, which is a standard treatment for patients with locally advanced or metastatic bladder cancer. Responses to erdafitinib were seen in patients who had previously not responded to anti PD-L1/PD-1 therapy.

Common adverse effects are increased phosphate level, mouth sores, fatigue, change in kidney function, diarrhea, dry mouth, nails separating from the bed or poor formation of the nail, change in liver function, low sodium levels, decreased appetite, change in sense of taste, anemia, dry skin, dry eyes, and hair loss.

Other adverse effects are redness, swelling, peeling or tenderness on the hands or feet, constipation, stomach pain, nausea, and muscle pain.

Erdafitinib may cause serious eye problems, including inflamed eyes, inflamed cornea, and disorders of the retina. Patients are advised to have eye examinations intermittently and to tell their health professional right away if they develop blurred vision, loss of vision, or other visual changes. Health professionals are advised to check patients? blood phosphate level between 14 and 21 days after starting treatment and monthly, and to increase the dose of erdafitinib in patients whose serum phosphate is below the target level.

Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment and for 1 month after the last dose. Pregnancy testing is recommended for females of reproductive potential before initiating treatment. Women who are pregnant or breastfeeding should not take erdafitinib because it may cause harm to a developing fetus or newborn baby.

Medication Monitor Categories:
New Drug Approvals

metastatic-bladder-cancer