Balversa® (erdafitinib)
3, 4, 5 mg tablets

Learn more about treatment with BALVERSA® at balversahcp.com

Erdafitinib (BALVERSA®) Is a Recommended Treatment Option in the

NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES®)[1]

FOR BLADDER CANCER

For previously-treated locally advanced or metastatic disease (Stage IV) patients with susceptible *FGFR3* genomic alterations:

NCCN Guidelines® Recommendations for erdafitinib (BALVERSA®)	NCCN Guidelines Preference Category
Previous immunotherapy – no previous enfortumab vedotin-ejtv or chemotherapy **Previous immunotherapy and enfortumab vedotin-ejtv –** no previous chemotherapy **Previous chemotherapy and immunotherapy –** no previous enfortumab vedotin-ejfv	**Preferred 2L systemic therapy**[1*†‡]
Previous chemotherapy – no previous immunotherapy or enfortumab vedotin-ejtv	**Other recommended 2L systemic therapy**[1*‡]
Previous chemotherapy, immunotherapy, and enfortumab vedotin-ejtv	**Preferred subsequent-line systemic therapy**[1†‡] (Category 1 for post-platinum + checkpoint inhibitor, if eligible)[§]

Indication

BALVERSA® (erdafitinib) is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible *FGFR3* genetic alterations whose disease has progressed on or after at least one line of prior systemic therapy.

Select patients for therapy based on an FDA-approved companion diagnostic for BALVERSA®.

Limitations of Use

BALVERSA® is not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

Information on FDA-approved tests for the detection of *FGFR3* genetic alterations in urothelial cancer is available at: https://www.fda.gov/CcompanionDiagnostics.

Important Safety Information

Warnings and Precautions include ocular disorders, hyperphosphatemia and soft tissue mineralization, and embryo-fetal toxicity.

Adverse Reactions

In the pooled safety population described in Warnings and Precautions, the median duration of treatment was 4.8 months (range: 0.1 to 43 months). The most common (>20%) adverse reactions, including laboratory abnormalities, were increased phosphate, nail disorders, stomatitis, diarrhea, increased creatinine, increased alkaline phosphatase, increased alanine aminotransferase, decreased hemoglobin, decreased sodium, increased aspartate aminotransferase, fatigue, dry mouth, dry skin, decreased phosphate, decreased appetite, dysgeusia, constipation, increased calcium, dry eye, palmar-plantar erythrodysesthesia syndrome, increased potassium, alopecia, and central serous retinopathy.

*NCCN Category 2A recommendation: Based upon lower-level evidence, there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
†Preferred Intervention: Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
‡Limitations of Use for erdafitinib (BALVERSA®): Not recommended for the treatment of patients who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.[2]
§NCCN Category 1 recommendations are based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.
2L = second-line; FDA = U.S. Food and Drug Administration; FGFR3 = fibroblast growth factor receptor; NCCN = National Comprehensive Cancer Network® (NCCN®); PD-L1/PD-1 = programmed death ligand 1/programmed cell death protein 1.

Efficacy of BALVERSA® (erdafitinib) was studied in a phase 3, randomized, open-label, multicenter study vs chemotherapy[2,3]

- Patients (N=266) had locally advanced or metastatic urothelial carcinoma that had progressed after 1 or 2 prior treatments, at least 1 of which included a PD-1 or PD-L1 inhibitor, and had selected *FGFR3* alterations/mutations identified in a central or local laboratory by PCR or NGS assays[2]
- Patients were randomized to BALVERSA® (8 mg with individualized up-titration to 9 mg) vs chemotherapy (docetaxel 75 mg/m^2 Q3W or vinflunine 320 mg/m^2 Q3W). Treatment was administered until unacceptable toxicity or progression[2]
- The primary efficacy endpoint was overall survival (OS) assessed by investigators according to RECIST v1.1; progression-free survival (PFS), objective response rate (ORR = confirmed complete response [CR] + partial response [PR]), and duration of response (DoR) were included as secondary efficacy endpoints[2]
- BALVERSA® provided a statistically significant improvement in OS vs chemotherapy (12.1 vs 7.8 months; HR=0.64; 95% CI: 0.47, 0.78; *P*=0.0050)[2]

An FDA-approved companion diagnostic test is available.[2] Information on FDA-approved tests for the detection of *FGFR3* genetic alterations in urothelial cancer is available at: https://www.fda.gov/CompanionDiagnostics

Important Safety Information

Warnings and Precautions

The safety population described in the Warnings and Precautions reflect a pooled safety population of 479 patients with advanced urothelial cancer and *FGFR* alterations who received BALVERSA®.

Ocular Disorders – BALVERSA® can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect.

CSR/RPED occurred in 22% of patients treated with BALVERSA®, with a median time to first onset of 46 days. In 104 patients with CSR, 40% required dose interruptions and 56% required dose reductions; 2.9% of BALVERSA®-treated patients required permanent discontinuation for CSR. Of the 24 patients who restarted BALVERSA® after dose interruption with or without dose reduction, 67% had recurrence and/or worsening of CSR after restarting. CSR was ongoing in 41% of the 104 patients at the time of last evaluation.

Dry eye symptoms occurred in 26% of BALVERSA®-treated patients. All patients should receive dry eye prophylaxis with ocular demulcents as needed.

Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms. Ophthalmological examination should include assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography. Withhold or permanently discontinue BALVERSA® based on severity and/or ophthalmology exam findings.

Hyperphosphatemia and Soft Tissue Mineralization – BALVERSA® can cause hyperphosphatemia leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of BALVERSA®. Increased phosphate occurred in 73% of BALVERSA®-treated patients. The median onset time of increased phosphate was 16 days (range: 8-421) after initiating BALVERSA®. Twenty-four percent of patients received phosphate binders during treatment with BALVERSA®. Vascular calcification was observed in 0.2% of patients treated with BALVERSA®.

Monitor for hyperphosphatemia throughout treatment. In all patients, restrict phosphate intake to 600-800 mg daily and avoid concomitant use of agents that may increase serum phosphate levels. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate level returns to <7.0 mg/dL. Withhold, dose reduce, or permanently discontinue BALVERSA® based on duration and severity of hyperphosphatemia.

Embryo-Fetal Toxicity – Based on the mechanism of action and findings in animal reproduction studies, BALVERSA® can cause fetal harm when administered to a pregnant female. In a rat embryo-fetal toxicity study, erdafitinib caused malformations and embryo-fetal death at maternal exposures that were less than the human exposures at the maximum human recommended dose based on AUC. Advise pregnant patients of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with BALVERSA® and for one month after the last dose.

Adverse Reactions

In the pooled safety population described in Warnings and Precautions, the median duration of treatment was 4.8 months (range: 0.1 to 43 months). The most common (>20%) adverse reactions, including laboratory abnormalities, were increased phosphate, nail disorders, stomatitis, diarrhea, increased creatinine, increased alkaline phosphatase, increased alanine aminotransferase, decreased hemoglobin, decreased sodium, increased aspartate aminotransferase, fatigue, dry mouth, dry skin, decreased phosphate, decreased appetite, dysgeusia, constipation, increased calcium, dry eye, palmar-plantar erythrodysesthesia syndrome, increased potassium, alopecia, and central serous retinopathy.

In Cohort 1 of the BLC3001 (NCT03390504, THOR) study:

- Serious adverse reactions occurred in 41% of patients who received BALVERSA®. Serious reactions in >2% of patients included urinary tract infection (4.4%), hematuria (3.7%), hyponatremia (2.2%), and acute kidney injury (2.2%). Fatal adverse reactions occurred in 4.4% of patients who received BALVERSA®, including sudden death (1.5%), pneumonia (1.5%), renal failure (0.7%), and cardiorespiratory arrest (0.7%).
- Permanent discontinuation of BALVERSA® due to an adverse reaction occurred in 14% of patients. Adverse reactions which resulted in permanent discontinuation of BALVERSA® in >2% of patients included nail disorders (3%) and eye disorders (2.2%).
- Dosage interruptions of BALVERSA® due to an adverse reaction occurred in 72% of patients. Adverse reactions which required dosage interruption in >4% of patients included nail disorders (22%), stomatitis (19%), eye disorders (16%), palmar-plantar erythrodysesthesia syndrome (15%), diarrhea (10%), hyperphosphatemia (7%), increased aspartate aminotransferase (6%), and increased alanine aminotransferase (5%).
- Dose reductions of BALVERSA® due to an adverse reaction occurred in 69% of patients. Adverse reactions which required dose reductions in >4% of patients included nail disorders (27%), stomatitis (19%), eye disorders (17%), palmar-plantar erythrodysesthesia syndrome (12%), diarrhea (7%), dry mouth (4.4%), and hyperphosphatemia (4.4%).
- Clinically relevant adverse reactions in <15% of patients who received BALVERSA® included nausea (15%), pyrexia (15%), epistaxis (13%), vomiting (10%), and arthralgia (10%).

CI = confidence interval; HR = hazard ratio; NGS = next generation sequencing; Q3W = every three weeks; RECIST = Response Evaluation Criteria In Solid Tumors.

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Important Safety Information (cont'd)

Drug Interactions

Effects of Other Drugs on BALVERSA®

- Moderate CYP2C9 or Strong CYP3A4 Inhibitors: Consider alternative agents; however, if co-administration is unavoidable, monitor closely for adverse reactions.
- Strong CYP3A4 inducers: Avoid co-administration with BALVERSA®.
- Moderate CYP3A4 inducers: If co-administration is required at the start of BALVERSA® treatment, administer BALVERSA® at a dose of 9 mg daily.
- Serum phosphate level-altering agents: Avoid co-administration with agents that can alter serum phosphate levels before the initial dose increase period based on serum phosphate levels.

Effect of BALVERSA® on Other Drugs

- P-gp substrates: If co-administration is unavoidable, separate BALVERSA® administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices.

Please click here to see full BALVERSA® Prescribing Information.

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References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Bladder Cancer V.2.2026. © National Comprehensive Cancer Network, Inc. 2026. Accessed July 9, 2026. All rights reserved. To view the most recent and complete version of the guideline, go online to www.nccn.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** BALVERSA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **3.** Loriot Y, Matsubara N, Park SH, et al. Erdafitinib or chemotherapy in advanced or metastatic urothelial carcinoma. *N Engl J Med.* 2023. doi: 10.1056/NEJMoa2308849 p. 3.

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