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ASIA EDITION

Balversa receives U.S. FDA approval for the treatment of patients with Urothelial Carcinoma

15 April 2019 | News

The approval follows FDA Breakthrough Therapy Designation in March 2018 and Priority Review Designation of the New Drug Application submitted in September 2018.

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced that BALVERSA received accelerated approval from the U.S. Food and Drug Administration (FDA) for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) which has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. BALVERSA is the first FGFR kinase inhibitor approved by the FDA. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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"I've spent my career specializing in the care of patients with metastatic urothelial carcinoma and understand the need for new treatments for this disease," said Arlene O. Siefker-Radtke, M.D., professor of Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center, and lead study investigator. "BALVERSA is an important new therapy for this small subset of patients with urothelial carcinoma who, up until now, had limited treatment options."

BALVERSA, a once-daily oral FGFR kinase inhibitor, received accelerated approval based on results from a Phase 2 clinical trial (BLC2001, NCT02365597), a multicenter, open-label, single-arm study, of 87 patients with disease that had progressed on or after at least one prior chemotherapy and that had at least one of the following genetic alterations: FGFR3 gene mutations (R248C, S249C, G370C, Y373C) or FGFR gene fusions (FGFR3-TACC3, FGFR3-BAIAP2L1, FGFR2-BICC1, FGFR2-CASP7), as determined by a clinical trial assay performed at a central laboratory.1 The results demonstrated a 32.2 percent objective response rate (ORR) as assessed by Blinded Independent Review Committee (BIRC) [95% CI(22.4, 42.0)].1 Responders included patients who had previously not responded to anti PD-L1/PD-1 therapy.1 In the trial, ORR was defined as the percentage of patients with measurable lesions achieving a complete response (CR) [2.3 percent] or partial

response (PR) [29.9 percent]1 to treatment using the Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) criteria, a standard way to measure how well a patient responds to treatment based on whether tumors shrink, stay the same, or get bigger as assessed per investigator.2 Results also showed a median duration of response (DoR) of 5.4 months [95% CI(4.2, 6.9)] in patients treated with BALVERSA.1There were no confirmed responses to BALVERSA in the FGFR2 fusion patient population (n=6).1 Data from the BLC2001 study were presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting and were recognized as a "Best of ASCO" selection.