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BALVERSA™ (erdafitinib) Receives U.S. FDA Approval for the Treatment of Patients with Locally Advanced or Metastatic Urothelial Carcinoma with Certain FGFR Genetic Alterations

- *BALVERSA is the first FGFR kinase inhibitor to receive U.S. FDA approval*
- *Simultaneous approval of companion diagnostic intended to identify a subset of patients most likely to benefit from BALVERSA, offering a personalized treatment approach*

HORSHAM, PA, April, 12 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that BALVERSA™ (erdafitinib) 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.[1] 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.[1] Today's approval follows FDA Breakthrough Therapy Designation in

March 2018 and Priority Review Designation of the New Drug Application submitted in September 2018.

"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.[1] There 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 (Abstract #4503) and were recognized as a "Best of ASCO" selection.

Warnings and Precautions include Ocular Disorders, Hyperphosphatemia and Embryo-fetal Toxicity.[1] The most common adverse reactions (ARs) including laboratory abnormalities $\geq$20% were phosphate increased (76%), stomatitis (56%), fatigue (54%), creatinine increased (52%), diarrhea (47%), dry mouth (45%), onycholysis (41%), alanine aminotransferase increased (41%), alkaline phosphatase increased (41%), sodium decreased (40%), decreased appetite (38%), albumin decreased (37%), dysgeusia (37%), hemoglobin decreased (35%), dry skin (34%), aspartate

aminotransferase increased (30%), magnesium decreased (30%), dry eye (28%), alopecia (26%), palmar-plantar erythrodysesthesia syndrome (26%), constipation (28%), phosphate decreased (24%), abdominal pain (23%), calcium increased (22%), nausea (21%), and musculoskeletal pain (20%). The most common Grade 3 or greater ARs (>1%) were stomatitis (9%), nail dystrophy*, palmar-plantar erythrodysesthesia syndrome (6%), paronychia (3%), nail disorder*, keratitis^, onycholysis (10%*) and hyperphosphatemia. (*Included within onycholysis. ^Included within dry eye.)[1]

The FDA simultaneously approved a companion diagnostic for use with BALVERSA, the QIAGEN *therascreen*® FGFR RGQ Reverse-transcription (RT)-polymerase chain reaction (PCR) Kit, which is the first PCR-based companion diagnostic approved to detect FGFR alterations. The *therascreen*® FGFR test detects the presence of FGFR alterations in the tumor tissue of patients with mUC.[1] If one or more of the genetic alterations or fusions are detected, the patient may be a candidate for treatment with BALVERSA. Information on FDA-approved tests for the detection of FGFR genetic alterations in urothelial carcinoma is available at: http://www.fda.gov/CompanionDiagnostics.

Janssen is offering BALVERSA and associated patient services through a single source specialty pharmacy provider, US Bioservices. This model is part of Janssen's ongoing commitment to provide high-quality products, services, access, and support to healthcare professionals and patients.

"We recognize the significant unmet need that persists in the treatment of men and women diagnosed with this form of urothelial carcinoma, and we have worked expeditiously to develop BALVERSA for patients in close consultation with the FDA," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We look forward to the continued development of BALVERSA to understand how this important new therapy may further inform the care of patients with metastatic urothelial carcinoma and its investigational use in other cancers where FGFR alterations may be present in the future."

"The FDA approval of BALVERSA represents our commitment to deliver much-needed therapies for devastating diseases, including metastatic urothelial carcinoma where there is a lack of therapeutic options," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. "We are also pleased to see the simultaneous FDA approval of a companion diagnostic with BALVERSA, which will offer a more personalized approach to therapy for healthcare professionals to treat their patients."

Full prescribing information will be available at www.BALVERSA.com.

About Urothelial Carcinoma

Urothelial carcinoma, also known as transitional cell carcinoma, starts in the innermost lining of the bladder.[3] It is the most common and frequent form of bladder cancer, representing more than 90 percent of all bladder cancers.[4] About one in five patients with mUC have a FGFR genetic alteration.[5,6] FGFRs are a family of receptor tyrosine kinases which can be activated by genetic alterations in a variety of tumor types, and these alterations may lead to increased tumor cell growth and survival.[7] BALVERSA is approved specifically for the treatment of patients with locally mUC harboring FGFR3 or FGFR2 genetic alterations. In the U.S., it is estimated that up to 3,000 people with urothelial carcinoma will test FGFR positive on an annual basis.[5,6,8,9] FGFR genetic alterations can be detected through an FDA-approved companion diagnostic. The five-year survival rate for patients with Stage IV metastatic bladder cancer that has spread to distant parts of the body is currently five percent.[10]

About BALVERSA™ (erdafitinib)

BALVERSA (erdafitinib) is a once-daily, oral fibroblast growth factor receptor (FGFR) kinase inhibitor indicated for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) which has susceptible FGFR3 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.[1] This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

The pivotal multicenter, open-label Phase 2 BLC2001 (NCT02365597) clinical trial evaluated the efficacy and safety of BALVERSA for the treatment of adults with mUC whose tumors have certain FGFR alterations. In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize BALVERSA. BALVERSA will be commercially available through the single-source specialty pharmacy provider US Bioservices.

For more information about BALVERSA, visit www.BALVERSA.com.

Indication

BALVERSA is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma which has

- susceptible FGFR3 or FGFR2 genetic alterations and
- progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

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

This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

BALVERSA™ (erdafitinib) Important Safety Information

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

CSR/RPED was reported in 25% of patients treated with BALVERSA, with a median time to first onset of 50 days. Grade 3 CSR/RPED, involving central field of vision, was reported in 3% of patients. CSR/RPED resolved in 13% of patients and was ongoing in 13% of patients at the study cutoff. CSR/RPED led to dose interruptions and reductions in 9% and 14% of patients, respectively and 3% of patients discontinued BALVERSA. Dry eye symptoms occurred in 28% of patients during treatment with BALVERSA and were Grade 3 in 6% of 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 BALVERSA when CSR occurs and permanently discontinue if it does not resolve within 4 weeks or if Grade 4 in severity. For ocular adverse reactions, follow the dose modification guidelines *[see Dosage and Administration (2.3)]*.

Hyperphosphatemia Increases in phosphate levels are a pharmacodynamic effect of BALVERSA *[see Pharmacodynamics (12.2)].* Hyperphosphatemia was reported as adverse reaction in 76% of patients treated with BALVERSA. The median onset time for any grade event of hyperphosphatemia was 20 days (range: 8 –116) after initiating BALVERSA. Thirty-two percent of patients received phosphate binders during treatment with BALVERSA Monitor for hyperphosphatemia and follow the dose modification guidelines when required *[see Dosage and Administration 2.2, 2.3]*.

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 woman. In a rat embryo-fetal toxicity study, erdafitinib was embryotoxic and teratogenic at exposures less than the human exposures at all doses studied. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception prior to and during treatment, 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 *[see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)]*.

Most common adverse reactions including laboratory abnormalities ≥ 20% were: phosphate increased(76%), stomatitis(56%), fatigue(54%), creatinine increased(52%), diarrhea(47%), dry mouth(45%), onycholysis(41%), alanine aminotransferase increased(41%), alkaline phosphatase increased(41%), sodium decreased(40%), decreased appetite(38%), albumin decreased(37%), dysgeusia(37%), hemoglobin decreased(35%), dry skin(34%), aspartate aminotransferase increased(30%), magnesium decreased(30%), dry eye(28%), alopecia(26%), palmar-plantar erythrodysesthesia syndrome(26%), constipation(28%), phosphate decreased(24%), abdominal pain(23%), calcium increased(22%), nausea(21%), and musculoskeletal pain(20%). The most common Grade 3 or greater ARs (>1%) were stomatitis(9%), nail dystrophy*, palmar-plantar erythrodysesthesia syndrome(6%), paronychia(3%), nail disorder*, keratitis^, onycholysis(10%*) and hyperphosphatemia. *Included within onycholysis. ^Included within dry eye.

An adverse reaction with a fatal outcome in 1% of patients was acute myocardial infraction.

Serious adverse reactions occurred in 41% of patients including eye disorders (10%).

Permanent discontinuation due to an adverse reaction occurred in 13% of patients. The most frequent reasons for permanent discontinuation included eye disorders (6%).

Dosage interruptions occurred in 68% of patients. The most frequent adverse reactions requiring dosage interruption included hyperphosphatemia (24%), stomatitis (17%), eye disorders (17%) and palmar-plantar erythrodysaesthesia syndrome (8%).

Dose reductions occurred in 53% of patients. The most frequent adverse reactions for dose reductions included eye disorders (23%), stomatitis (15%), hyperphosphatemia (7%), palmar-plantar erythrodysaesthesia syndrome (7%), paronychia (7%) and nail dystrophy (6%).

Drug Interactions

- Strong CYP2C9 or CYP3A4 Inhibitors - Consider alternative agents or monitor closely for adverse reactions. (7.1)
- Strong CYP2C9 or CYP3A4 inducers: Avoid concomitant use with BALVERSA. (7.1)
- Moderate CYP2C9 or CYP3A4 inducers: Increase BALVERSA dose up to 9 mg. (7.1)
- Serum phosphate level-altering agents: Avoid concomitant use with agents that can alter serum phosphate levels before the initial dose modification period. (2.3, 7.1)
- CYP3A4 substrates: Avoid concomitant use with sensitive CYP3A4 substrates with narrow therapeutic indices. (7.2)
- OCT2 substrates: Consider alternative agents or consider reducing the dose of OCT2 substrates based on tolerability. (7.2)
- P-gp substrates: Separate BALVERSA administration by at least 6 hours before or after administration of P-gp substrates with narrow therapeutic indices, (7.2)

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding BALVERSA™ (erdafitinib). The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of

future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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