News Release

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Janssen Announces BALVERSA® (erdafitinib) Improved Overall Survival Versus Chemotherapy in Patients with Metastatic or Unresectable Urothelial Carcinoma and Selected Fibroblast Growth Factor Receptor Gene Alterations After Prior Anti-PD-(L)1 Treatment

Confirmatory Data from Cohort 1 of the Phase 3 THOR Study Showed Greater Than Four-Month Improvement in Median Overall Survival in Patients Treated with BALVERSA® Versus Chemotherapy

CHICAGO, June 5, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from an interim analysis of Cohort 1 of the Phase 3 THOR study, evaluating treatment with BALVERSA® (erdafitinib) versus chemotherapy in patients with metastatic or unresectable urothelial carcinoma (UC) and selected fibroblast growth factor receptor (FGFR) gene alterations who had received prior treatment with an anti-programmed death ligand 1 (PD-[L]1) agent. In this cohort, the study met its primary endpoint of overall survival (OS) and reduced the risk of death by 36 percent.[1] Following the accelerated approval of BALVERSA® in 2019, these confirmatory data were featured in a Late-Breaking Presentation Session (Abstract # LBA4619) at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting.

"These results represent the first data from a randomized, controlled trial evaluating BALVERSA® for the treatment of patients with FGFR-altered urothelial carcinoma, who often experience poor disease outcomes," said Yohann Loriot*, M.D., Ph.D., Institut Gustave Roussy

and University of Paris-Saclay, France, and principal study investigator. "The use of BALVERSA® in this setting supports recommendations for FGFR testing in all patients with metastatic urothelial cancer."

THOR (NCT03390504) is a Phase 3 randomized, open-label, multicenter study evaluating the efficacy and safety of BALVERSA®. Patients were categorized to one of two cohorts based on the type of prior therapy they had received: prior treatment with an anti-PD-(L)1 agent (Cohort 1) or prior treatment not containing an anti-PD-(L)1 agent (Cohort 2). Patients in Cohort 1 were randomized to receive either BALVERSA® or chemotherapy in a 1:1 ratio and patients in Cohort 2 were randomized to receive either BALVERSA® or pembrolizumab in a 1:1 ratio. The primary endpoint of the study is OS; progression-free survival (PFS), objective response rate (ORR), duration of response (DOR), patient-reported outcomes, safety and pharmacokinetics (PK) are secondary endpoints.[2]

Results from the interim analysis of Cohort 1 included data inclusive of 266 patients where 136 patients were assigned to BALVERSA® and 130 were randomized to chemotherapy. Median follow-up was 15.9 months. At the data cutoff on January 15, 2023, OS in patients who received BALVERSA® was 12.1 months compared to 7.8 months in patients who received chemotherapy (Hazard Ratio (HR) 0.64; [95 percent Confidence Interval (CI), 0.47-0.88]; p=0.0050).[1] Treatment with BALVERSA® also showed an improvement in median PFS compared to chemotherapy of 5.6 months versus 2.7 months (HR 0.58; [95 percent CI, 0.44-0.78]; p=0.0002) and an ORR of 45.6 percent versus 11.5 percent (Relative Risk (RR) 3.94; [95 percent CI, 2.37-6.57]; p<0.001).[1] These data met the predefined criteria for superiority, and the independent data safety monitoring committee recommended that the study be stopped at the interim analysis and that all patients randomized to chemotherapy be offered the opportunity to cross-over to BALVERSA®.[1]

Across all subgroups, OS benefit with BALVERSA® versus chemotherapy was consistently observed. Subgroups included FGFR alteration type, baseline Eastern Cooperative Oncology Group performance status, lines of prior treatment, visceral metastasis, primary tumor location and type of chemotherapy.[1]

The safety profile of BALVERSA® observed in THOR was consistent with the known safety profile of BALVERSA® in metastatic urothelial carcinoma (mUC). Serious treatment-related adverse events (TRAEs) were observed in 13.3 percent of patients who received BALVERSA®

and 24.1 percent of patients randomized to chemotherapy, and grade three or higher adverse events were observed in 45.9 percent of patients on BALVERSA® and 46.4 percent on chemotherapy.[1] 8.1 percent of patients who received BALVERSA® and 13.4 percent of patients who received chemotherapy had TRAEs that lead to discontinuation of therapy.[1] Central serous retinopathy occurred in 17 percent of patients who received BALVERSA®.[1] TRAEs leading to death were reported in one patient who received BALVERSA® and six patients who received chemotherapy.[1]

Final Results from Phase 2 NORSE Study Evaluating BALVERSA® and Cetrelimab Combination Therapy

Also presented were data from the Phase 2 NORSE study evaluating BALVERSA® alone and in combination with cetrelimab, an investigational anti-programmed death receptor-1 (PD-1) monoclonal antibody, as first-line treatment of patients with mUC who were ineligible for cisplatin-based chemotherapy and who had FGFR alterations. Both the combination and monotherapy treatment demonstrated a clinically meaningful response, with an ORR of 54.5 percent (95 percent CI, 38.8-69.6) in the combination arm and 44.2 percent (95 percent CI, 29.1-60.1) in the monotherapy arm, and was well-tolerated in patients. In the combination arm, six patients achieved a complete response and one patient in the monotherapy arm achieved a complete response. Median PFS in the combination arm was 11.0 months (95 percent CI, 5.45-13.63), versus 5.6 months (95 percent CI, 4.34-7.36) in the monotherapy arm. Grade three or higher TRAEs were observed in 45.5 percent of patients who received BALVERSA® and cetrelimab combination therapy and 46.5 percent of patients who received BALVERSA® monotherapy.[3]

Results from the Phase 2 RAGNAR Study Evaluating the Efficacy and Safety of BALVERSA®

Additionally, data from the phase 2 RAGNAR study, evaluating the efficacy and safety of BALVERSA® in patients with advanced or metastatic solid tumors with prespecified FGFR alterations, regardless of tumor location or histology (tumor-agnostic), were also presented at ASCO this year. Treatment with BALVERSA® demonstrated a clinically meaningful response at a median follow-up of 17.9 months, with an ORR of 30 percent (95 percent CI, 24-36). Responses were observed across 16 distinct tumors. Among the 64 responding patients, three percent of patients had a complete response and 27 percent of patients had a partial response.

Grade three or higher TRAEs were observed in 46 percent of patients who received BALVERSA®. Serious TRAEs were observed in 8.3 percent of patients and no deaths due to TRAEs were observed.[4]

"Janssen's ongoing evaluation of BALVERSA® reinforces our commitment to improving outcomes for people diagnosed with bladder cancer and to identify therapeutic solutions for late-stage as well as early stage disease," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "Through ongoing trials, including the Phase 3 THOR study and the Phase 2 NORSE and RAGNAR studies, we continue to add to the growing body of evidence supporting the impact of this important targeted therapy in bladder cancer and with other tumor types with FGFR genetic alterations."

BALVERSA® received accelerated approval from the FDA as a targeted therapy for adult patients with locally advanced or mUC with 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[5]

About THOR

THOR (NCT03390504) is a Phase 3 randomized, open-label, multicenter study evaluating the efficacy and safety of BALVERSA®. The study compares BALVERSA® with standard of care treatments chemotherapy or pembrolizumab in patients with metastatic or unresectable UC with selected FGFR genetic alterations that has progressed during or after one or two prior lines of therapy, at least one of which includes an anti-PD-(L)1 agent (Cohort 1) or one prior treatment not containing an anti-PD-(L)1 agent (Cohort 2). The trial consists of screening, a treatment phase (from randomization until disease progression, intolerable toxicity, withdrawal of consent or decision by investigator to discontinue treatment) and a post-treatment follow-up (from end-of-treatment to participant's death, withdraws consent, lost to follow-up study completion for the respective cohort, whichever comes first). A long-term extension period is planned for after the clinical cutoff date is achieved for the final analysis of each cohort and eligible patients will continue to benefit from the study intervention. The primary endpoint of the study is OS; PFS, ORR, DOR, patient-reported outcomes, safety and PK are secondary endpoints.[2]

About NORSE

NORSE (NCT03473743) is an open-label, Phase 1b/2 multicenter study of BALVERSA® in combination with cetrelimab in patients with locally advanced or metastatic urothelial cancer and FGFR3 or FGFR2 gene alterations. Participants enrolled in Phase 1b may have received any number of lines of prior therapy, and participants enrolled in Phase 2 had no prior systemic therapy for metastatic disease and are ineligible for cisplatin-based chemotherapy, currently the standard of care. Phase 1b established the recommended Phase 2 dose (RP2D) for BALVERSA® in combination with cetrelimab, and Phase 2 evaluates the safety and efficacy of the RP2D. The study is being conducted in three phases: screening phase, treatment phase and follow-up phase. Study evaluations include efficacy, pharmacokinetics, pharmacodynamics, immunogenicity, biomarkers and safety.[8]

About RAGNAR

RAGNAR (NCT04083976) is a Phase 2 clinical trial evaluating the safety and efficacy of BALVERSA® in patients with advanced solid tumors, regardless of cancer type or tumor location (tumor-agnostic), driven by FGFR1–4 alterations. Patients in the trial have progressed on or after at least one line of systemic therapy and have no alternative standard treatment options. Following screening by local molecular testing or central NGS, patients are enrolled in four separate cohorts: a broad panel cohort of patients with pathogenic FGFR mutations or gene fusions (tumor histologies evaluated include but are not limited to cholangiocarcinoma [bile duct cancer], high- and low-grade glioma [a tumor type occurring in the brain or spinal cord], breast, pancreatic, squamous and non-squamous non-small cell lung cancer, colorectal, endometrial, esophageal, salivary gland, ovarian, duodenal [cancer occurring in the first part of the small intestine], thyroid and cancer of unknown primary origin); an exploratory cohort of patients with other FGFR mutations; a cholangiocarcinoma expansion cohort; and a pediatric cohort of patients ages six to 17 with FGFR alterations.[1]

The primary endpoint of RAGNAR is independent review committee assessed ORR. Key secondary endpoints include investigator-assessed ORR, DOR, disease control rate (DCR), clinical benefit rate, PFS, OS and incidence and severity of adverse events.

About BALVERSA®

BALVERSA® (erdafitinib) is a once-daily, oral FGFR kinase inhibitor that is approved by the U.S. FDA for the treatment of adults with locally advanced or mUC that has susceptible FGFR3 or FGFR2 genetic alterations and has progressed during or following at least one line of

platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Patients are selected for therapy based on an FDA-approved companion diagnostic for BALVERSA®. Information on FDA-approved tests for the detection of FGFR genetic alterations in urothelial cancer is available at: http://www.fda.gov/CompanionDiagnostics. 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.[5,6]

In addition to the Phase 3 THOR study, BALVERSA® is being studied in the Phase 2 THOR-2/BLC2003 study (NCT04172675) study examining BALVERSA® versus investigator choice of intravesical chemotherapy in participants who received Bacillus Calmette-Guérin and recurred with high risk non-muscle-invasive bladder cancer; the Phase 2 RAGNAR (NCT04083976) study assessing BALVERSA® in patients with advanced solid tumors and FGFR genetic alterations; and the Phase 1b/2 NORSE (NCT03473743) study evaluating BALVERSA® in combination with cetrelimab in patients with locally advanced or mUC with FGFR3 or FGFR2 genetic alterations who are ineligible for cisplatin.[2,7,8]

In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize BALVERSA®.

For more information, visit www.BALVERSA.com.

About Cetrelimab

Administered intravenously, cetrelimab is an investigational anti-programmed cell death receptor-1 (PD-1) monoclonal antibody being studied to treat bladder cancer, prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Janssen portfolio.

About Urothelial Carcinoma

Urothelial carcinoma, also known as transitional cell carcinoma, starts in the innermost lining of the bladder.[9] It is the most common and frequent form of bladder cancer, representing more than 90 percent of all bladder cancers.[10] Approximately one in five patients (20 percent) diagnosed with mUC have an FGFR genetic alteration.[11,12] Fibroblast growth factor receptors are a family of receptor tyrosine kinases that can be activated by genetic alterations in a variety of tumor types, and these alterations may lead to increased tumor cell growth and survival.[13] In the U.S. each year, it is estimated that up to 3,000 people with urothelial

carcinoma will test positive for FGFR genetic alterations.[8,14,15,16] Select fibroblast growth factor receptor 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 eight percent.[17]

BALVERSA® IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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 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® *[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®.

Cutaneous calcinosis, non-uremic calciphylaxis and vascular calcification have been observed in 0.3% of patients treated with BALVERSA®.

Monitor for hyperphosphatemia throughout treatment. In all patients, restrict phosphate intake to 600-800 mg daily. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate level returns to <5.5 mg/dL. Withhold, dose reduce, or permanently discontinue BALVERSA® based on duration and severity of hyperphosphatemia *[see Dosage and Administration (2.3), Table 2: Dose Modifications for Adverse Reactions]*.

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 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 *[see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)]*.

Most common adverse reactions including laboratory abnormalities ≥20%:
Phosphate increased (76%), stomatitis (56%), fatigue (54%), creatinine increased (52%), diarrhea (47%), dry mouth (45%), nail disorder (45%), 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 adverse reactions (>1%) were stomatitis (9%), nail dystrophy*, palmar-plantar erythrodysesthesia syndrome (6%), paronychia (3%), nail disorder (10%), keratitis†, and hyperphosphatemia (1%).

*Included within nail disorder. †Included within dry eye.

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

infarction.

- 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 erythrodysesthesia 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 erythrodysesthesia syndrome (7%), paronychia (7%), and nail dystrophy (6%).

Drug Interactions

- Moderate CYP2C9 or strong 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)

Use in Specific Populations

Lactation – Because of the potential for serious adverse reactions from erdafitinib in a breastfed child, advise lactating women not to breastfeed during treatment with BALVERSA® and for one month following the last dose.

Please see the full Prescribing Information for BALVERSA®.

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 & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenGlobal and @JanssenUS. Janssen Research & Development, LLC, and Janssen Biotech, Inc., belong to 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 product development and the potential benefits and treatment impact of 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, Janssen Biotech, Inc., 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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 Janssen Research & Development, LLC, Janssen Biotech, Inc., 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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*Dr. Loriot has served as a consultant to Janssen; he has not been paid for any media work.

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[1] Loriot et al. Phase 3 THOR Study: Results of erdafitinib (erda) versus chemotherapy (chemo) in patients (pts) with advanced or metastatic urothelial cancer (mUC) with select fibroblast growth factor receptor alterations (FGFRalt). ASCO 2023.

[2] Clinicaltrials.gov. A Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Participants With Advanced Urothelial Cancer and Selected Fibroblast Growth Factor Receptor (FGFR) Gene Aberrations. https://clinicaltrials.gov/ct2/show/NCT03390504. Accessed May 2023.

[3] Siefker-Radtke et al. Erdafitinib (ERDA) vs ERDA plus cetrelimab (ERDA+CET) for patients (pts) with metastatic urothelial carcinoma (mUC) and fibroblast growth factor receptor alterations (FGFRa): Final results from the phase 2 Norse study. ASCO 2023.

[4] Loriot et al. Tumor agnostic efficacy and safety of erdafitinib in patients (pts) with advanced solid tumors with prespecified fibroblast growth factor receptor alterations (FGFRalt) in RAGNAR: Interim analysis (IA) results. ASCO 2023.

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