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Janssen Presents Results from Phase 1b/2 NORSE Study in Patients with Metastatic or Locally Advanced Urothelial Carcinoma Treated with Erdafitinib in Combination with Cetrelimab, a PD-1 Inhibitor

Oral presentation at ESMO Annual Congress 2021 – featured in a late-breaking abstract – reports efficacy and safety of erdafitinib in combination with a PD-1 inhibitor in bladder cancer

September 17, 2021 (BEERSE, BELGIUM) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 1b/2 NORSE (NCT03473743) study evaluating erdafitinib in combination with cetrelimab, an anti-programmed cell death protein 1 (PD-1) monoclonal antibody, compared to erdafitinib monotherapy in patients with locally advanced or metastatic urothelial carcinoma (mUC) with fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations who are ineligible for cisplatin, a current standard of care treatment for mUC. The results were highlighted in an oral presentation at the European Society for Medical Oncology (ESMO) Annual Congress 2021 virtual meeting on Friday, September 17 (Abstract #LBA27).[1] Preliminary findings suggest robust clinical activity and depth of response in patients treated with erdafitinib in combination with cetrelimab.[1] The overall safety of treatment with erdafitinib in combination with cetrelimab was generally consistent with erdafitinib monotherapy and aligned with the known safety profile of approved anti–PD-1 therapies.[1]

At the time of analysis, the investigator-assessed objective response rate (ORR) in 19 patients treated with erdafitinib in combination with cetrelimab was 68 percent (95 percent confidence interval [CI]; 43-87), of which 21 percent (n=4) were complete responses (CR) and 47 percent were partial responses (PR). The disease control rate (DCR) was 90 percent (95 percent CI; 67-

99) for evaluable patients using the Response Evaluation Criteria in Solid Tumours Version 1.1* (RECIST v1.1) criteria.[1] The ORR in 18 patients treated with erdafitinib monotherapy was 33 percent (95 percent CI; 13-59), in which one patient showed a CR and 28 percent (n=5) were PR. The DCR was 100 percent (95 percent CI; 82-100).[1]

"People with advanced bladder cancer face an urgent need for new treatment options as current therapies are not suitable for all patients and do not always lead to adequate long-term outcomes," said Dr Ignacio Durán**, Medical Oncologist, Margues de Valdecilla University Hospital, Santander, Spain. "The potential of precision oncology is to treat cancer patients using a personalised approach, tailored to their unique genetic composition, lifestyle and environment. The NORSE clinical study marks another important step forward in changing the prognosis for people living with specific genetic alterations associated with advanced bladder cancer."

Fibroblast growth factor receptors are a family of receptor tyrosine kinases that can be activated by genetic alterations in a variety of tumour types, potentially leading to increased tumour cell growth and survival.[2] Approximately 20 percent of patients diagnosed with mUC have an FGFR genetic alteration.[2] A current standard of care for mUC is cisplatin-based chemotherapy, however, more than 50 percent of patients with mUC may be ineligible for cisplatin treatment, underscoring a need for new treatment options.[3] Alternative options for patients with newly diagnosed mUC include different chemotherapy regimens or PD-1 inhibitors, which enhance T-cell immune responses against the tumour cells.[4]

The findings presented at ESMO build upon the growing set of erdafitinib data. In 2019 the U.S. Food and Drug Administration (FDA) granted accelerated approval to erdafitinib, with a companion diagnostic, as a once-daily oral FGFR kinase inhibitor for patients with mUC that have susceptible FGFR3 and 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.[5] This indication is approved under accelerated approval based on tumour response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[5] Within EMEA, erdafitinib has since been approved for use in Israel, Jordan and the Kingdom of Saudi Arabia.[6,7,8]

The safety profile of erdafitinib in combination with cetrelimab (n=24) was generally similar to that of erdafitinib monotherapy (n=24), with the most common treatment-emergent adverse events (AEs) being hyperphosphataemia (erdafitinib in combination with cetrelimab vs erdafitinib monotherapy, 58 percent vs 58 percent), stomatitis (54 percent vs 63 percent), diarrhoea (42

percent vs 50 percent), dry mouth (58 percent vs 21 percent), dry skin (38 percent vs 21 percent) and anaemia (25 percent vs 25 percent).[1] Grade 3-4 AEs occurred in 12 patients (50 percent) in the erdafitinib in combination with cetrelimab arm and 9 patients (38 percent) in the erdafitinib arm.[1] In the erdafitinib in combination with cetrelimab arm, the most frequent Grade 3-4 AEs were stomatitis (n=3 [12.5 percent]), lipase increased (n=3 [12.5 percent]), and fatigue (n=2 [8.3 percent]); in the erdafitinib arm, these were anaemia (n=3 patients [12.5 percent]) and general physical health deterioration (n=3 [12.5 patients]).[1]

"People living with bladder cancer often face a poor prognosis. This needs to change, and it is a challenge the scientific community can collectively overcome," said Dr Catherine Taylor, Vice President, Medical Affairs for Europe, Middle East and Africa, Therapeutic Area Strategy, Jan-Cil Zug. "Precision medicine in bladder cancer has the potential ambition to one day not only eliminate cancer, but in the meantime, to change what a cancer diagnosis means, giving back time and quality of life to people living with the disease. To date, there have been limited treatment options for patients living with specific genetic mutations, including FGFR alterations. The research presented today at ESMO paves the way for future solutions that are better tailored to the individual and address an area of significant unmet medical need."

*RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumours, which is a standard way to measure how well solid tumours respond to treatment and is based on whether tumours shrink, remain the same or increase in size.[9]

**Dr Ignacio Durán has been a paid consultant for Janssen. He has not been compensated for any media work.

About the NORSE Study[10]

NORSE (NCT03473743) is an open-label, Phase 1b/2 multicenter study of erdafitinib 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 erdafitinib 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. Enrollment of the Phase 2 part of the NORSE study is currently ongoing.

About Urothelial Carcinoma

The prevalence of bladder cancer is around three times higher in Europe than anywhere else in the world, other than North America.[11] Approximately 151,000 people in Europe are diagnosed with bladder cancer every year and incidence rates are continuing to rise.[11,12] Urothelial carcinoma, also known as transitional cell carcinoma, starts in the innermost lining of the bladder. It is the most common and frequent form of bladder cancer, representing more than 90 percent of all bladder cancers.[13] Approximately one in five patients (20 percent) diagnosed with mUC have an FGFR genetic alteration.[2] Fibroblast growth factor receptors are a family of receptor tyrosine kinases that can be activated by genetic alterations in a variety of tumour types, and these alterations may lead to increased tumour cell growth and survival.[2] The five-year survival rate for patients with Stage IV metastatic bladder cancer that has spread to distant parts of the body is currently 6 percent.[14]

About Erdafitinib

Erdafitinib is a once-daily oral FGFR kinase inhibitor being evaluated by Janssen Research & Development in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer.[15] In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Therapeutics Ltd. to develop and commercialise erdafitinib.

About Cetrelimab

Cetrelimab is a Janssen discovered and developed investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied in the treatment of bladder cancer, prostate cancer, and multiple myeloma as a combination treatment.[10,16,17] Cetrelimab is also being evaluated in multiple combination regimens across the Janssen oncology portfolio.

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.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, and/or 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 29, 2019, 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson 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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