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Janssen Submits New Drug Application to U.S. FDA Seeking Approval of Erdafitinib for the Treatment of Metastatic Urothelial Cancer

HORSHAM, PA, September 18, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that a New Drug Application (NDA) has been submitted to the U.S. Food and Drug Administration (FDA) seeking approval of erdafitinib for the treatment of patients with locally advanced or metastatic urothelial cancer (UC) and certain fibroblast growth factor receptor (FGFR) genetic alterations whose tumors have progressed after prior chemotherapy. Erdafitinib is an investigational, once-daily, oral pan-FGFR inhibitor that received Breakthrough Therapy Designation from the FDA in March 2018.

"Erdafitinib has demonstrated promising results in the treatment of metastatic urothelial cancer, a disease where patients unfortunately have limited treatment options today," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "We look forward to working with the FDA in the agency's review of the application as we believe erdafitinib will provide patients with an important therapeutic option."

The NDA submission is based on data from the BLC2001 (NCT02365597) Phase 2 clinical trial, which evaluated the efficacy and safety of erdafitinib in the treatment of adult patients with locally advanced or metastatic UC, whose tumors have certain FGFR alterations. The primary endpoint of this study was the percentage of participants with objective response, defined as Complete Response or Partial Response based on Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1* criteria. The study results were recently presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in Chicago (Abstract #4503) and were recognized as a "Best of ASCO" selection.

"The erdafitinib FDA submission is an important milestone as we work to bring a new treatment option to patients diagnosed with metastatic urothelial cancer," said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, LLC. "Our organizational focus on areas of high unmet medical need underscores our commitment to advancing transformational science and developing solutions that may prolong and improve patient lives."

*****RECIST (version 1.1) refers to Response Evaluation Criteria in Solid Tumors, which is a standard way to measure how well a cancer patient responds to treatment and is based on whether tumors shrink, stay the same, or get bigger.[1]

For information about Janssen's pre-approval access program, visit https://www.janssen.com/compassionate-use-pre-approval-access/our-policy-and-principles.

About Urothelial Cancer

Urothelial cancer, most frequently in the bladder, is the sixth most common type of cancer in the U.S.[2] In 2018, an estimated 81,190 new cases of bladder cancer will be diagnosed in the U.S. and an estimated 17,240 bladder cancer deaths will occur.[2] The relative five-year survival rate for patients with Stage IV metastatic bladder cancer is currently five percent.[3] Patients with metastatic urothelial cancer, who have FGFR genetic alterations, have poor prognoses and a high unmet need based on low response rates and may be resistant to treatment with immune-checkpoint inhibitors.[4]

About Erdafitinib

Erdafitinib is an investigational, once-daily oral pan-fibroblast growth factor receptor (FGFR) inhibitor being studied in Phase 2 and Phase 3 clinical trials for the treatment of patients with locally advanced or metastatic urothelial cancer.[5] 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.[6] A companion diagnostic to identify patients with FGFR alterations is an integral part of the development program for erdafitinib. In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize erdafitinib.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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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 product development and the potential benefits and treatment impact of 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 of Johnson & Johnson 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Reports on Form 10-Q and in 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 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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[3] Bladder Cancer: Statistics. Available at: https://www.cancer.net/cancer-types/bladder-cancer/statistics. Accessed September 2018.
[4] Siefker-Radtke, A, et al. First results from the primary analysis population of the phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRalt). *Journal of Clinical Oncology*. Abstract #4503.
[5] Tabernero J, Bahleda R, Dienstmann R, Infante JR, Mita A, Italiano A, Calvo E, Moreno V, Adamo B, Gazzah A, et al. Phase I dose-escalation study of JNJ-42756493, an oral pan-fibroblast growth factor receptor inhibitor, in patients with advanced solid tumors. J Clin Oncol. 2015;33:3401–3408. doi: 10.1200/JCO.2014.60.7341.
[6] Dienstmann R, Rodon J, Prat A, et al. Genomic aberrations in the FGFR pathway: Opportunities for targeted therapies in solid tumors. Ann Oncol. 2014;25:552–563.