Media Inquiries:
Brian Kenney
Phone: 1-215-620-0111

Satu Glawe
Phone: +49 172 294 6264

Investor Relations:
Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:
1-800-526-7736

Erdafitinib Phase 2 Study Results Show Promise in the Treatment of Metastatic Urothelial Cancer

- *Treatment with investigational compound erdafitinib demonstrated durable responses in patients with metastatic urothelial cancer with genetic alterations*
- *Data featured for the first time as an oral presentation at ASCO 2018 (Abstract #4503) and selected for the Best of ASCO Meetings*

Chicago Ill., June 3, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced findings today from a Phase 2 study that showed treatment with erdafitinib, a once-daily oral pan-fibroblast growth factor receptor (FGFR) inhibitor, resulted in durable responses in patients with metastatic or surgically unresectable urothelial cancer (mUC) and FGFR alterations (FGFRalt), a population with high unmet need based on poor outcomes when treated with available therapies. FGFRs are cell proteins that, if altered, can contribute to the development of cancer. Alterations occur in approximately 20 percent of mUC patients. The results were presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in Chicago (Abstract #4503) and have been selected for the Best of ASCO Meetings.

“Despite the improvements in outcomes reported with immune checkpoint inhibitors, the majority of patients do not respond to treatment. Additionally, there is no targeted therapy approved for treating specific subsets of patients with urothelial cancer who have genetic alterations,” said Arlene O. Siefker-Radtke, M.D., Professor of Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center, and lead study investigator. “These encouraging Phase 2 data showed

treatment with erdafitinib resulted in promising response rates and progression-free survival in an important patient population."

BLC2001 (NCT02365597) is a multicenter, open-label Phase 2 study evaluating the efficacy and safety of erdafitinib in the treatment of adult patients with locally advanced or metastatic urothelial cancer, whose tumors have certain FGFR alterations. Ninety-nine patients were treated with an optimized dosing schedule using pharmacodynamically guided dose up-titration: a starting dose of erdafitinib at 8 mg daily, with the possibility to increase the dose to 9 mg daily based on serum phosphate levels. Twelve percent of patients were chemo-naïve, 89 percent of patients had received one or more lines of therapy, 43 percent of patients had received two or more prior lines of therapy, and 78 percent of patients had visceral metastases. There was a 40 percent confirmed overall response rate (RECIST 1.1;* 3% Complete Response, 37% Partial Response), a median progression-free survival of 5.5 months and median overall survival of 13.8 months. In patients who experienced grade 3 adverse events (AEs), the most common were stomatitis (9%), hand-foot syndrome (5%) and diarrhea (4%). Seven patients discontinued due to treatment-related AEs.

"We are pleased to present these data here at ASCO with the Phase 2 results of the efficacy and safety of erdafitinib in the treatment of metastatic or surgically unresectable urothelial cancer with FGFR alterations," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Janssen Research & Development, LLC. "Following the U.S. Food and Drug Administration Breakthrough Therapy Designation in March 2018, our aim is to move toward regulatory submission with the Phase 2 data and continue to pursue erdafitinib in Phase 3 clinical development, as well as in combination with anti-PD-1 therapy."

*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]

About Urothelial Cancer

Urothelial cancer starts in the urothelial cells that line the inside of the bladder.[2] This cancer is the most prevalent among bladder cancers, which constitute the sixth most common type of cancer in the U.S.[2] In 2018, an estimated 81,190 new cases of bladder cancer are expected, resulting in 17,240 deaths.[2] For patients with metastatic disease, outcomes can be dire due to the often rapid

progression of the tumor and the lack of efficacious treatments, especially in relapsed or refractory disease.[2] The relative five-year survival rate for patients with metastatic disease is five percent.[2]

About Erdafitinib

Erdafitinib is a once-daily oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated by Janssen Research & Development in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer.[3] FGFRs are a family of receptor tyrosine kinases, which may be upregulated in various tumor cell types and may be involved in tumor cell proliferation, tumor angiogenesis and tumor cell survival.[4] In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Therapeutics Ltd. 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 the 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; 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," and in the company'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 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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[1] National Cancer Institute. NCI Dictionary of Cancer Terms. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/recist. Accessed May 2018.
[2] National Cancer Institute. Cancer Stat Facts: Bladder Cancer. Available at: https://seer.cancer.gov/statfacts/html/urinb.html. Accessed April 2018.
[3] 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.
[4] 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.