



Media Inquiries:

Brian Kenney
Phone: 1-215-628-7010

Satu Glawe
Phone: +49 172 294 6264

Investor Relations:

Lesley Fishman
Phone: 1-732-524-3922

U.S. Medical Inquiries:

1-800-526-7736

**Janssen Announces U.S. FDA Breakthrough Therapy Designation for Erdafitinib
in the Treatment of Metastatic Urothelial Cancer**

Erdafitinib, an oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor, shows promise as the first targeted agent for patients with metastatic urothelial cancer, one of the most common cancers

RARITAN, NJ, March 15, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for erdafitinib in the treatment of urothelial cancer. Urothelial cancer, most frequently in the bladder, is the sixth most common type of cancer in the U.S.¹ A Breakthrough Therapy Designation is granted to expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life-threatening condition.² The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.²

“For patients diagnosed with urothelial cancer, outcomes are unfortunately disheartening due to the aggressiveness of the disease,” said Peter Lebowitz, MD, PhD, Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “Through the continued development of erdafitinib, and working closely with the FDA, we look forward to bringing a potential new treatment option to patients.”

The Breakthrough Therapy Designation is based on data from a multicenter, open-label Phase 2 clinical trial evaluating the efficacy and safety of erdafitinib in the treatment of adult patients with locally advanced or metastatic urothelial cancer, whose tumors have certain fibroblast growth factor receptor (FGFR) genetic alterations. The Phase 2 study BLC2001 presented at the 2018 ASCO Genitourinary Cancers Symposium showed an overall response rate of 42 percent in 59 patients with relapsed/refractory metastatic urothelial cancer whose tumors harbored actionable FGFR mutations (ASCO-GU abstract #411).³

About Urothelial Cancer

Urothelial cancer, also known as transitional cell cancer, is the sixth most common type of cancer in the U.S.¹ These cancers start in the urothelial cells that line the inside of the bladder.⁴ In 2018, an estimated 81,190 new cases of bladder cancer are expected, resulting in 17,240 deaths.⁴ 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. The relative five-year survival rate for patients with metastatic disease is five percent.¹

About Erdafitinib

Erdafitinib is an oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated by Janssen in Phase 2 and 3 clinical trials in patients with advanced urothelial cancer. FGFRs are a family of receptor tyrosine kinases which may be upregulated in various tumor cell types and may be involved in tumor cell differentiation and proliferation, tumor angiogenesis, and tumor cell survival.⁵ 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.

¹ National Cancer Institute. Cancer Stat Facts: Bladder Cancer. Available at: <https://seer.cancer.gov/statfacts/html/urinb.html>. Accessed February 2018.

² The U.S. Food and Drug Administration. "Expedited Programs for Serious Conditions." Available at: <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>. Accessed February 2018.

³ Loriot, Yohann, et al. Erdafitinib (JNJ-42756493), a Pan-Fibroblast Growth Factor Receptor Inhibitor, in Patients with Metastatic or Unresectable Urothelial Carcinoma and FGFR Alterations: Phase 2 Continuous vs Intermittent Dosing. 2018 Genitourinary Cancers Symposium, February 8-10, 2018, San Francisco, CA. Abstract #411.

⁴ American Cancer Society. Cancer Facts & Figures 2017. Atlanta, Ga: American Cancer Society; 2017.

⁵ National Cancer Institute. NCI Drug Dictionary. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-drug/def/pan-fgfr-kinase-inhibitor-bgj398>. Accessed February 2018.