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**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 were selected for the [Best of ASCO 2018 Meetings](#)*

BEERSE, BELGIUM, 3 June, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced findings today from a Phase 2 study that showed treatment with erdafitinib resulted in durable responses in patients with metastatic or surgically unresectable urothelial cancer (mUC) and fibroblast growth factor receptor alterations (FGFRalt). This is a patient population with high unmet need based on poor outcomes when treated with available therapies. Erdafitinib is a once-daily pan-FGFR inhibitor.¹ FGFRs are cell proteins that, if altered, can contribute to the development of cancer.¹ Alterations occur in approximately 20 percent of mUC patients.¹ 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.¹

“I am very encouraged by these Phase 2 data showing that erdafitinib had promising response rates and progression-free survival in a patient population with such high unmet need,” said Dr. Yohann Loriot, Senior Consultant, Department of Cancer Medicine & INSERM, Institut Gustave Roussy, University of Paris Sud, Villejuif, France. “Currently there are no targeted therapies approved for specific subsets of patients with urothelial cancer who have genetic alterations. While immune

checkpoint inhibitors have led to improvements in outcomes for these patients, we are still finding that many patients do not respond to treatment.”

BLC2001 ([NCT02365597](https://clinicaltrials.gov/ct2/show/study/NCT02365597)) is a multicentre, 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 tumours have certain FGFR alterations.¹ Ninety-nine patients were treated with an optimised 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.² 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.² There was a 40 percent confirmed overall response rate¹ (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.² In patients who experienced grade 3 adverse events (AEs), the most common were, stomatitis (9%) and diarrhoea (4%).¹ Seven patients discontinued due to treatment-related AEs.²

“These study results are very promising, particularly as this is an area of high unmet need with patients who otherwise have very limited treatment options remaining. We hope that the response rates shown by erdafitinib could eventually give patients with metastatic or surgically unresectable urothelial cancer a new treatment option,” said Dr Ivo Winiger-Candolfi, Europe, Middle East and Africa (EMEA) Oncology Therapeutic Area Lead, Janssen. “The successful development of new oncology therapies, such as erdafitinib, is an example of our precision medicine approach: providing the right patient, with the right treatment, at the right time. We recognise that every patient is unique and that by accounting for individual differences in people’s genes, environments and lifestyles, we can optimise the therapeutic benefit for particular groups of patients. We look forward to understanding the potential efficacy and broader safety profile of erdafitinib in both Phase 3 development as well as in combination with anti-PD1 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 tumours shrink, stay the same, or get bigger.³

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About Urothelial Cancer

Europe has among the highest incidence rates of bladder cancer in the world and mortality rates for men are by far the highest recorded worldwide.⁴ It is the fifth most frequently diagnosed cancer in the EU, with about 124,000 new cases each year for both sexes.⁵ The majority (90%) of bladder cancer consists of urothelial carcinoma in Western Europe.⁶ Urothelial bladder cancer starts in the bladder lining (urothelial cells or transitional cells) and can be non-invasive or invasive.⁷ For patients with metastatic disease, outcomes can be poor due to the often rapid progression of the tumour and the lack of efficacious treatments.⁸ The relative five-year survival rate for patients with metastatic disease is five percent.⁹

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.¹⁰ FGFRs are a family of receptor tyrosine kinases which may be upregulated in various tumour cell types and may be involved in tumour cell proliferation, tumour angiogenesis and tumour cell survival.¹¹ In 2008, Janssen entered into an exclusive worldwide license and collaboration agreement with Astex Therapeutics Ltd. to develop and commercialise erdafitinib.

Erdafitinib received Breakthrough Therapy Designation from the U.S. Food and Drug Administration in [March 2018](#).¹² The aim is to move towards 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.

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/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

Cilag GmbH International; Janssen Biotech, Inc.; Janssen Oncology, Inc. and Janssen-Cilag International NV are part 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 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-Cilag International NV, 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; 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 behaviour 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 Siefker-Radtke AO, Necchi A, Park SH, 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). *J Clin Oncol*. 2018;36(Suppl.):abstract 4503.

² Siefker-Radtke AO, 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). Oral presentation at ASCO Annual Meeting, Chicago, IL, USA; 1-5 June 2018.

³ National Cancer Institute. NCI Dictionary of Cancer Terms. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/recist>. Accessed May 2018.

⁴ Antoni S, Ferlay J, Soerjomataram I, Znaor A, Jemal A, Bray F. Bladder cancer incidence and mortality: a global overview and recent trends. *Eur Urol*. 2017;71:96-108.

⁵ European Commission. Epidemiology of bladder cancer in Europe. Available at: <https://ec.europa.eu/jrc/en/publication/epidemiology-bladder-cancer-europe> Last accessed May 2018.

⁶ Wong MC, Fung FD, Leung C, Cheung WW, Goggins WB, Ng CF. The global epidemiology of bladder cancer: a joinpoint regression analysis of its incidence and mortality trends and projection. *Sci Rep*. 2018;8:1129.

- ⁷ Macmillan Cancer Support. Types of bladder cancer. Available at: <https://www.macmillan.org.uk/information-and-support/bladder-cancer/non-invasive-bladder-cancer/understanding-cancer/types-of-bladder-cancer.html> Last accessed May 2018.
- ⁸ Waldron, Nick et al, Current management of advanced bladder cancer. Available at: <https://onlinelibrary.wiley.com/doi/pdf/10.1002/tre.603>. Last accessed May 2018.
- ⁹ National Cancer Institute. Cancer Stat Facts: Bladder Cancer. Available at: <https://seer.cancer.gov/statfacts/html/urinb.html>. Last accessed May 2018.
- ¹⁰ 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.
- ¹¹ National Cancer Institute. NCI Drug Dictionary: pan FGFR kinase inhibitor BGJ398. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-drug/def/pan-fgfr-kinase-inhibitor-bgj398> Last accessed May 2018.
- ¹² Janssen. Janssen announces U.S. FDA breakthrough therapy designation for erdafitinib in the treatment of metastatic urothelial cancer. Press release March 15, 2018. Available at: <http://www.janssen.com/janssen-announces-us-fda-breakthrough-therapy-designation-erdafitinib-treatment-metastatic> Last accessed May 2018.