News Release

Media Contacts:
Suzanne Frost
+1 416-317-0304

Brian Kenney
+1 215-620-0111

Investor Relations:
Raychel Kruper
Investor-relations@its.jnj.com

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

First Results with Erdafitinib-Releasing Intravesical Delivery System (TAR-210) Show Early Evidence of Positive Clinical Activity in Patients with Non-Muscle-Invasive Bladder Cancer with Select Fibroblast Growth Factor Receptor Alterations

Investigational TAR-210 first-in-human results highlight the potential for local sustained release of erdafitinib with a novel intravesical delivery system

Phase 1 results show a manageable safety profile with limited systemic toxicity, and early complete responses in patients with high-risk and intermediate-risk NMIBC

MADRID, October 22, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first results from an open-label, multicenter Phase 1 study evaluating the safety and efficacy of TAR-210, an intravesical delivery system designed to provide sustained, local release of erdafitinib into the bladder in patients with non-muscle-invasive bladder cancer (NMIBC) with select fibroblast growth factor receptor (FGFR) alterations. These data were featured today in a Late-Breaking Mini-Oral Presentation Session (Abstract #LBA104) at the European Society for Medical Oncology (ESMO) 2023 Congress taking place October 20-24 in Madrid, Spain.[1]

Results featured data from Cohort 1 [(C1); patients with recurrent, Bacillus Calmette-Guérin (BCG)-unresponsive high-risk (HR) NMIBC (high-grade Ta/T1; papillary only) who refused or were ineligible for radical cystectomy] and Cohort 3 [(C3); patients with intermediate-risk (IR) NMIBC (Ta/T1) low-grade papillary disease] left in situ as tumor marker lesions.

At the data cutoff of 29 August 2023, 43 patients had been treated with TAR-210 across the two cohorts. Of the 16 patients in C1 with HR NMIBC having at least one response assessment, 82 percent were recurrence-free (RF). Median duration of treatment exposure was 3.7 months, with 94 percent of the 16 patients still on study. In C3, 87 percent of the 27 patients having at least one response assessment with IR NMIBC achieved a complete response (CR). Median duration of treatment exposure was 4.2 months.

The most common treatment-related adverse events (TRAEs) were Grade 1/2 lower urinary tract TRAEs. There were no dose-limiting toxicities and no deaths. Two patients discontinued the study due to TRAEs of low-grade urinary symptoms and one patient had serious TRAEs of pyelonephritis and sepsis.

"Patients with high- or intermediate-risk non-muscle-invasive bladder cancer have seen limited advancement in the treatment landscape over the last 50 years and the available options are associated with a high risk of recurrence and significant side effect burden," said Antoni Vilaseca,* M.D., Ph.D. of the Hospital Clínic de Barcelona and presenting author of the Phase 1 TAR-210 study. "We look forward to further results from this study in the future and the ongoing development of the localized delivery of erdafitinib."

"We are advancing this novel technology with the ambition of bringing bladder-sparing and BCG-free regimens to patients with localized bladder cancer," said Jeffrey Infante, M.D., Global Head, Oncology Early Clinical Development and Translational Research, Janssen Research & Development, LLC. "These encouraging results reinforce our commitment to improving patient outcomes by treating early-stage disease with this intravesical delivery technology."

About TAR-210

TAR-210 is an investigational erdafitinib intravesical delivery system. The safety and efficacy of TAR-210 is being evaluated in a Phase 1 study (NCT05316155) in patients with muscle-invasive bladder cancer (MIBC) and NMIBC. The study categorizes patients into four cohorts based on their disease presentation. Cohort 1 (C1) includes patients with recurrent, BCG-unresponsive high-risk NMIBC with concomitant high-grade papillary disease who have refused or are ineligible for radical cystectomy (RC). Cohort 2 (C2) includes patients with the same presentation, but who are scheduled for RC. Cohort 3 (C3) includes patients with

recurrent, intermediate-risk NMIBC with a history of low-grade papillary disease. To be eligible for C3, the presence of visible tumor(s) is required. Cohort 4 (C4) includes patients with muscle-invasive bladder cancer. The primary endpoint of the study is safety (adverse events, including dose-limiting toxicity). Secondary endpoints include pharmacokinetics (PK), RF survival in patients in C1 and C2, CR rate and duration of CR in patients in C3 and pathologic CR rate in C4.[2]

About Non-Muscle-Invasive Bladder Cancer

Non-muscle-invasive bladder cancer (NMIBC) is cancer found in the tissue that lines the inner surface of the bladder. The bladder muscle is not involved. Patients are categorized into one of three risk groups which describe how likely the cancer is to progress, spread further, or come back after treatment: low-risk, intermediate-risk or high-risk. Radical cystectomy is currently recommended for NMIBC patients who fail Bacillus Calmette-Guérin (BCG) therapy, with over 90 percent cancer-specific survival if performed before muscle-invasive progression.[3,4] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.[5] The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[4,6]

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: Oncology, Immunology, Neuroscience, Cardiovascular, Pulmonary Hypertension, and Retina.

Learn more at www.janssen.com. Follow us at @JNJInnovMed and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. are Johnson & Johnson companies.

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 TAR-210 or 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; Janssen Biotech, Inc., 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; 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 January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson'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 Janssen Research & Development, Janssen Biotech, Inc., nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**Dr. Vilaseca has not been paid for any media work.*

###

---

[1] Vilaseca A, et al. First Safety and Efficacy Results of the TAR-210 Erdafitinib Intravesical Delivery System in Patients with Non–Muscle-Invasive Bladder Cancer (NMIBC) With Select FGFR Alterations. ESMO 2023. Abstract.
[2] https://ascopubs.org/doi/abs/10.1200/JCO.2023.41.6_suppl.TPS583
[3] Claps F, et al. BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer: Current Treatment Landscape and Novel Emerging Molecular Targets. *Int J Mol Sci.* 2023;24(16):12596.
[4] Brooks NA, O'Donnell MA. Treatment options in non-muscle-invasive bladder cancer after BCG failure. *Indian J Urol.* 2015;31(4):312-319. doi:10.4103/0970-1591.166475.
[5] Guancial EA, et al. Bladder cancer in the elderly patient: challenges and solutions. *Clin Interv Aging.* 2015; 10: 939–949.
[6] Chamie K, et al. Recurrence of high-risk bladder cancer: A population-based analysis. *Cancer.* 2013. 119(17): 3219–3227.