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News Release

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First Results with Erdafitinib-Releasing Intravesical Delivery System (TAR-210) Show Early Evidence of 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.[1]

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

High Wycombe, United Kingdom, 22 October 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first results from an open-label, multicentre 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.[1] These data were featured today in a Late-Breaking Mini-Oral Presentation Session at the European Society for Medical Oncology (ESMO) 2023 Congress taking place 20-24 October in Madrid, Spain (Abstract #LBA104).[1]

"Our ambition is to not only improve clinical outcomes for patients living with bladder cancers, but to also address unmet needs in terms of improving quality of life," said Martin Vogel, EMEA Therapeutic Area Lead Oncology, Janssen-Cilag GmbH. "We are committed to advancing

how bladder cancer is treated across the spectrum of this disease. Early results from the TAR-210 study of this intravesical drug delivery system motivate us to work even harder towards bringing this approach to patients."

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 tumour marker lesions.[1]

At the data cutoff of 29 August 2023, 43 patients had been treated with TAR-210 across the two cohorts.[1] Of the 16 patients in C1 with HR NMIBC having at least one response assessment, 82 percent were recurrence-free (RF).[1] Median duration of treatment exposure was 3.7 months, with 94 percent of the 16 patients still on study.[1] In C3, 87 percent of the 27 patients having at least one response assessment with IR NMIBC achieved a complete response (CR).[1] Median duration of treatment exposure was 4.2 months.[1]

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

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About TAR-210

TAR-210 is an investigational erdafitinib intravesical delivery system.[1] 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.[2] The study categorises patients into four cohorts based on their disease presentation.[2,3] 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).[3] Cohort 2 (C2) includes patients with the same presentation, but who are scheduled for RC.[3] Cohort 3 (C3) includes patients with recurrent, intermediate-risk NMIBC with a history of low-grade papillary disease.[3] To be eligible for C3, the presence of visible tumour(s) is required.[2] Cohort 4 (C4) includes patients with MIBC scheduled for RC, refusing or ineligible for platinum based chemotherapy[2,3] The primary endpoint of the study is safety (adverse events, including dose-limiting toxicity).[2,3]

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.[3]

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

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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 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 materialise, actual results could vary materially from the expectations and projections of Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies 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 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 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 Pharmaceutica NV, Janssen Research & Development, LLC, Janssen-Cilag Limited 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] 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. 2023 European Society for Medical Oncology. Oral presentation, 2023 ESMO Annual Meeting. October 22, 2023.
[2] Clinicaltrials.gov. Study of Erdafitinib Intravesical Delivery System for Localized Bladder Cancer. Available at: https://clinicaltrials.gov/study/NCT05316155. Last accessed October 2023.
[3] Vilaseca, A et al. Safety and efficacy of the erdafitinib (erda) intravesical delivery system, TAR-210, in patients (pts) with non-muscle-invasive bladder cancer (NMIBC) or muscle-invasive bladder cancer (MIBC) harboring select *FGFR* mutations or fusions: Phase 1 first-in-human study. *Journal of Clinical Oncology*. 2023;41(6)_suppl.TPS583.
[4] Urology Care Foundation. Non-muscle Invasive Bladder Cancer. Available at: https://urologyhealth.org/urology-a-z/n/non-muscle-invasive-bladder-cancer). Last accessed October 2023.
[5] Isharwal S, Konety B. Non-muscle invasive bladder cancer risk stratification. Indian J Urol. 2015 Oct-Dec;31(4):289-96. doi: 10.4103/0970-1591.166445. PMID: 26604439; PMCID: PMC4626912. Last accessed October 2023.
[6] 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. Last accessed October 2023.