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News Release

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TAR-200 Intravesical Delivery System Results Show 77 Percent Complete Response Rate in Patients with Bacillus-Calmette Guérin Unresponsive, High-Risk Non-Muscle-Invasive Bladder Cancer

Phase 2b SunRISe-1 study results showed sustained, durable complete responses beyond one year with intravesical gemcitabine delivery system.¹

BEERSE, BELGIUM, 22 October, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that data from Cohort 2 of the Phase 2b SunRISe-1 study evaluating the efficacy and safety of TAR-200 monotherapy in patients with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non-muscle-invasive bladder cancer (HR-NMIBC) CIS (carcinoma in situ)-positive who are ineligible for, or decline radical cystectomy, showed that 77 percent of patients (23 out of 30 [95 percent Confidence Interval (CI), 58-90]) achieved a complete response (CR). 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 #LBA105).¹

TAR-200 is an investigational intravesical drug delivery system designed to provide sustained local release of gemcitabine into the bladder.¹ Interim results from the [SunRISe-1](#) study were featured earlier this year at the American Urological Association Annual Meeting.² Results presented today included an evaluation of 54

patients (median age of 71; range 40-85; around 33 percent with concurrent papillary disease) who received TAR-200 monotherapy. Centrally confirmed CR by urine cytology and/or biopsy was achieved in 23 of 30 patients (CR 77 percent [95 percent CI, 58-90]) and investigator confirmed CR was achieved in 24 out of 30 patients (CR 80 percent [95 percent CI, 61-92]).¹ Twenty-one out of 23 responders had ongoing CR with 11 patients maintaining their CR for six months or more, and six patients had ongoing CR for 12 months or more. Median duration of response (DOR) was not reached.¹

"Patients with NMIBC, who are unresponsive to BCG, immunotherapy treatments are at high risk for disease progression, and unfortunately, available treatment options remain limited," said Andrea Necchi*, M.D., of Italy's Vita-Salute San Raffaele University and the IRCCS San Raffaele Hospital and Scientific Institute and a presenting author of the study. "The results of TAR-200 observed in this study present a potential less-invasive option for patients in the future."

Treatment-related adverse events (TRAEs) occurred in 29 patients (54 percent). The most common (≥ 10 percent) were pollakiuria, dysuria, micturition urgency, and hematuria. Four patients (seven percent) had Grade 3 or higher TRAEs and one patient (two percent) had ≥ 1 serious TRAEs. Two patients (four percent) had TRAEs leading to discontinuation and no deaths were reported.¹

"Currently, standard-of-care for BCG-unresponsive HR-NMIBC is radical cystectomy, however, it is associated with significant rates of morbidity, mortality, and impact on quality of life," commented Martin Vogel, EMEA Therapeutic Area Lead Oncology, Janssen-Cilag GmbH. "The findings of the SunRISe-1 study show that TAR-200 monotherapy can result in complete response in a significant number of patients, and highlight the potential of this innovative intravesical drug delivery system with further investigation."

Bladder cancer is the tenth most common cancer worldwide, with more than 570,000 patients diagnosed each year, and more than 200,000 new cases every year across Europe alone.³

“The current treatment options for patients with HR-NMIBC, who are unresponsive to BCG, remain limited and typically include repeat BCG therapy or radical cystectomy,” said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Janssen Research & Development, LLC. “Our goal is to transform the treatment landscape for patients with bladder cancer through innovative approaches that focus on bladder preservation and long-term survival.”

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About SunRISe-1

SunRISe-1 ([NCT04640623](https://clinicaltrials.gov/ct2/show/study/NCT04640623)) is a randomised, parallel-assignment, open-label Phase 2 clinical study evaluating the safety and efficacy of TAR-200 in combination with cetrelimab, TAR-200 alone, or cetrelimab alone for BCG-unresponsive HR-NMIBC CIS patients who are ineligible for, or decline, radical cystectomy.⁴ Participants are randomised to one of three cohorts: treatment with TAR-200 in combination with cetrelimab (Cohort 1), TAR-200 alone (Cohort 2), or cetrelimab alone (Cohort 3).⁴ The primary endpoint is CR rate at any time point. Secondary endpoints include DOR, overall survival, pharmacokinetics, quality of life, safety, and tolerability.⁴ Cohorts 1 and 3 were closed to further enrollment, effective June 1, 2023.¹

About TAR-200

TAR-200 is an investigational drug delivery system, enabling sustained release of gemcitabine into the bladder, increasing the amount of time the drug delivery system spends in the bladder and sustaining local drug exposure.^{5,6} The safety and efficacy of TAR-200 are being evaluated in Phase 2 and Phase 3 studies in patients with muscle-invasive bladder cancer in SunRISe-2 ([NCT04658862](https://clinicaltrials.gov/ct2/show/study/NCT04658862))⁷ and SunRISe-4 ([NCT04919512](https://clinicaltrials.gov/ct2/show/study/NCT04919512)),⁸ and NMIBC in SunRISe-1 and SunRISe-3 ([NCT05714202](https://clinicaltrials.gov/ct2/show/study/NCT05714202)).⁹

About Cetrelimab

Administered intravenously, cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied to treat bladder cancer^{10,11} prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Janssen Oncology portfolio.

About High-risk Non-Muscle-Invasive Bladder Cancer

High-risk non-muscle-invasive bladder cancer (HR-NMIBC) is a type of non-invasive bladder cancer that is more likely to recur or spread beyond the lining of the bladder, called the urothelium, and progress to invasive bladder cancer compared to low-risk NMIBC.¹² HR-NMIBC is characterised by a high-grade, large tumour size, presence of multiple tumours, and CIS.^{13,14} 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.¹⁵ Given that bladder cancer typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.^{16,17} The high rates of recurrence and progression can pose significant morbidity and distress for these patients.^{18,19}

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/emea. Follow us at www.linkedin.com/janssenEMEA for our latest news. Janssen Pharmaceutica NV, Janssen-Cilag GmbH, and Janssen Research & Development, LLC 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-200 and cetrelimab. 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 GmbH, 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; 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 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 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.

**Dr. Necchi has served as a consultant to Janssen; he has not been paid for any media work.*

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- ² Daneshmand S, et al. First results from SunRISe-1 in Patients with BCG Unresponsive High-Risk Non-Muscle-Invasive Bladder Cancer Receiving TAR-200 in Combination with Cetrelimab, TAR-200, or Cetrelimab Alone. Abstract LBA02-03, 2023 American Urological Association. April 2023.
- ³ GLOBOCAN 2020. Bladder cancer factsheet. Available at: <https://gco.iarc.fr/today/data/factsheets/cancers/30-Bladder-fact-sheet.pdf>. Last accessed October 2023.
- ⁴ Clinicaltrials.gov. A Study of TAR-200 in Combination With Cetrelimab, TAR-200 Alone, or Cetrelimab Alone in Participants With Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Intravesical Bacillus Calmette-Guérin Who Are Ineligible for or Elected Not to Undergo Radical Cystectomy (SunRISe-1). Available at: [Study Details | A Study of TAR-200 in Combination With Cetrelimab, TAR-200 Alone, or Cetrelimab Alone in Participants With Non-Muscle Invasive Bladder Cancer \(NMIBC\) Unresponsive to Intravesical Bacillus Calmette-Guérin Who Are Ineligible for or Elected Not to Undergo Radical Cystectomy | ClinicalTrials.gov](#). Last accessed October 2023.
- ⁵ Janssen.com. Janssen Oncology Strengthens Disease Interception Focus with TARIS' Unique Delivery System. Available at <https://www.janssen.com/oncology/janssen-oncology-strengthens-disease-interception-focus-taris-unique-delivery-system>. Last accessed October 2023.
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