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For Immediate Release

New data from TAR-200 Phase 2b SunRISe-1 study show 84 percent complete response rate in patients with high-risk non-muscle-invasive bladder cancer

Investigational TAR-200 monotherapy demonstrates high complete response rate without the need for reinduction or additive therapy in patients who are Bacillus Calmette-Guérin (BCG)-unresponsive

BARCELONA, September 15, 2024 /PR Newswire/ – Johnson & Johnson (NYSE:JNJ) announced today additional results from the pivotal Phase 2b SunRISe-1 study, supporting the safety and efficacy profile of investigational TAR-200 for the treatment of patients with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non-muscle-invasive bladder cancer (HR-NMIBC). New data were featured in a late-breaking oral presentation at the European Society of Medical Oncology (ESMO) 2024 Congress (Abstract #LBA85).

“The safety and efficacy profile observed across multiple patient cohorts in the SunRISe-1 study further supports the potential of TAR-200 for patients with high-risk non-muscle-invasive bladder cancer as an innovative targeted releasing system,” said Michiel S. van der Heijden, M.D., Ph.D., medical oncologist at Netherlands Cancer Institute. “These results support the potential of this novel treatment approach for patients who are not responsive to BCG immunotherapy and who face life-altering options, such as radical cystectomy.”

Pivotal Cohort 2 (TAR-200 monotherapy):
New results from all 85 patients enrolled in the pivotal cohort show a high, centrally-confirmed, single-agent complete response (CR) rate of 83.5 percent (95 percent confidence interval [CI], 74-91). Results show highly durable CRs without the need for reinduction, with 82 percent of patients maintaining response after a median follow-up of 9 months, and an estimated 12-month CR rate of 57.4 percent based on the Kaplan-Meier curve. The overall risk-benefit profile favors TAR-200 monotherapy (Cohort 2) in this patient population.[1] Earlier results from Cohort 2 were previously presented at the 2024 American

Urological Association (AUA) Annual Meeting.

Cohorts 1 and 3 (TAR-200 plus cetrelimab [CET] and CET monotherapy, respectively):
First results from Cohort 1 showed a 67.9 percent centrally-confirmed CR (95 percent CI, 54-80; 28-66, respectively). The first results from Cohort 3 (CET monotherapy) showed a 46.4 percent centrally-confirmed CR. The overall risk-benefit profile favors TAR-200 monotherapy (Cohort 2) in this patient population. The CET monotherapy CR rate is numerically similar to previously published CR rates from this class of therapies.[1]

"Our mission, to stay in front of cancer, drives us to innovate in ways that truly redefine treatment paradigms for patients with bladder cancer," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Innovative Medicine, Johnson & Johnson. "The data from our SunRISe clinical program illuminate the possibility of an innovative approach in an outpatient setting with the potential to impact patient well-being and enhance the entire treatment experience."

Low discontinuation rates due to treatment-resistant adverse events (TRAEs) were seen with TAR-200 (Cohort 2, six percent) and CET (Cohort 3, seven percent) alone, with higher rates in the combination (Cohort 1, TAR-200 26 percent or CET 23 percent). The most common (>20 percent) TRAEs of any grade across Cohort 1 and 2 were pollakiuria, dysuria, hematuria and urinary tract infection. No treatment-related deaths were reported.[1]

About Bladder Cancer

Bladder cancer is the ninth most common cancer in the world.[2] Although BCG immunotherapy has been accepted as the standard of care for nearly five decades, 30-40 percent of patients do not respond to BCG and experience disease recurrence or progression.[3] In such scenarios, radical cystectomy (removal of the bladder and neighboring structures and organs) emerges as the primary treatment option. This major abdominal procedure requires a urinary diversion to be created to collect and store urine.[4]

About TAR-200
TAR-200 is an investigational targeted releasing system designed to provide extended local release of gemcitabine into the bladder. It is installed in a physician's office setting during a 2-3 minute procedure with no anesthesia. In December 2023, the FDA granted TAR-200 Breakthrough Therapy Designation (BTD) for the potential future treatment of patients with BCG-unresponsive HR-NMIBC, who are ineligible for or elected not to undergo radical cystectomy (surgical removal of the bladder).

About SunRISe-1
SunRISe-1 (NCT04640623) is a randomized, 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 carcinoma in situ (CIS) patients who are ineligible for, or elected not to undergo, radical cystectomy. Participants are randomized to 1 of 4 cohorts: treatment with TAR-200 in combination with cetrelimab (Cohort 1), TAR-200 alone (Cohort 2), cetrelimab alone

(Cohort 3), or TAR-200 alone for papillary disease only (Cohort 4). The primary endpoint for Cohorts 1-3 is CR rate at any time point. Secondary endpoints include duration of response, overall survival, pharmacokinetics, quality of life, safety, and tolerability. Cohorts 1 and 3 were closed to further enrollment effective June 1, 2023.

About TAR-200
TAR-200 is an investigational targeted releasing system, enabling extended release of gemcitabine into the bladder, increasing the amount of time the drug delivery system spends in the bladder and sustaining local drug exposure. The safety and efficacy of TAR-200 are being evaluated in Phase 2 and Phase 3 studies in patients with MIBC in SunRISe-2 and SunRISe-4, and NMIBC in SunRISe-1, SunRISe-3 and SunRISe-5.

About Cetrelimab
Cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied for the treatment of bladder cancer, prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens.

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.[5,6] HR-NMIBC makes up 15-44 percent of patients with NMIBC and is characterized by a high-grade, large tumor size, presence of multiple tumors, and CIS. Radical cystectomy is currently recommended for NMIBC patients who fail BCG therapy, with over 90% cancer-specific survival if performed before muscle-invasive progression.[7,8] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.[9] The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[5,9]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at https://www.jnj.com/ or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us at @JanssenUS and @JNJInnovMed. Janssen Research & Development, LLC, Janssen Biotech, Inc., and Janssen Global Services, 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 or 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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC 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 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, 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, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC 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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*Dr. Michiel S. van der Heijden has provided consulting, advisory, and speaking services to Johnson & Johnson; they have not been paid for any media work.

Source: Johnson & Johnson

[1] Van der Heijden M., et al. TAR-200 +/- Cetrelimab and Cetrelimab Alone in Patients With Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer: Updated Results From SunRISe-1. ESMO 2024. September 15, 2024.

[2] Globocan 2022 https://gco.iarc.who.int/media/globocan/factsheets/populations/900-world-fact-sheet.pdf

[3] Zlotta AR, Fleshner NE, Jewett MA. The management of BCG failure in non-muscle-invasive bladder cancer: an update. *Can Urol Assoc J.* 2013;3(6-S4):199.

[4] Bladder removal surgery: What is a radical cystectomy? Bladder Cancer Advocacy Network. Accessed April 1, 2024. https://bcan.org/bladder-removal-surgery/.

[5] Grab-Heyne K, Henne C, Mariappan P, et al. Intermediate and high-risk non–muscle-invasive bladder cancer: an overview of epidemiology, burden, and unmet needs. *Front Oncol.* 2023;13:1170124.

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[8] Guancial EA, Roussel B, Bergsma DP, et al. Bladder cancer in the elderly patient: challenges and solutions. *Clin Interv Aging.* 2015;10:939-949.

[9] Chamie K, Litwin MS, Bassett JC, et al. Recurrence of high-risk bladder cancer: A population-based analysis. *Cancer.* 2013;119(17):3219-3227.