Johnson&Johnson

Media contacts:
Suzanne Frost
+1 416 317-0304

Brian Kenney
+1 215 620-0111

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

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

Johnson & Johnson's Investigational TAR-200 Granted U.S. FDA Breakthrough Therapy Designation for the Treatment of High-Risk Non-Muscle-Invasive Bladder Cancer

Breakthrough Therapy Designation for Novel Targeted Releasing System Based on Results from Ongoing Phase 2b SunRISe-1 Study

RARITAN, N.J., Dec. 4, 2023 – Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has granted TAR-200 Breakthrough Therapy Designation (BTD) for the potential future treatment of patients with Bacillus Calmette-Guérin (BCG)-unresponsive high-risk non-muscle-invasive bladder cancer (HR-NMIBC), who are ineligible for or elected not to undergo radical cystectomy (surgical removal of the bladder). TAR-200 is a novel investigational targeted releasing system designed to provide sustained local release of gemcitabine into the bladder. Today's BTD marks Johnson & Johnson's 13th such designation in oncology.

"TAR-200 represents a novel interventional approach for the treatment of localized bladder cancer where today, unfortunately, options are limited and include antiquated BCG therapy or radical cystectomy," said Kiran Patel, M.D., Vice President, Clinical Development, Solid Tumors, Johnson & Johnson Innovative Medicine. "This Breakthrough Therapy Designation recognizes TAR-200 as a promising advancement and marks an important step forward in our innovative focus to transform the treatment of bladder cancer."

The BTD is supported by data from SunRISe-1 (NCT04640623), an open-label Phase 2b 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.[1] Data from the SunRISe-1 study were featured during the 2023 European Society for Medical Oncology Annual Congress as a late-breaking mini-oral presentation (Abstract #LBA105) and interim results were presented at the 2023 American Urological Association Annual Meeting (Abstract #LBA02-03).

A U.S. FDA BTD is granted to expedite the development and regulatory review of a medicine that is intended to treat a serious or life-threatening condition and is based on preliminary clinical evidence that demonstrates the drug may have substantial improvement over available therapies on a clinically significant endpoint(s).[2]

About SunRISe-1

SunRISe-1 (NCT04640623) is an open-label Phase 2b 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 were randomized 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). The primary endpoint is Complete Response 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 controlled release of gemcitabine into the bladder, sustaining local drug exposure for weeks at a time. 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 and SunRISe-4 and NMIBC in SunRISe-1 and SunRISe-3.

About Cetrelimab

Administered intravenously, 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 regimen.

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- and intermediate risk NMIBC.[3,4] 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 are unresponsive to 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 unable to undergo radical cystectomy.[7] The high rates of recurrence and progression can pose significant morbidity and distress for patients with NMIBC.[8]

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 and Janssen Biotech, Inc. are both 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., 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.

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1 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: https://clinicaltrials.gov/study/NCT04640623. Last accessed: November 2023.

2 The U.S. Food and Drug Administration. "Expedited Programs for Serious Conditions." Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf. Last accessed: November 2023.

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