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NEWS RELEASE

Johnson & Johnson's TAR-200 monotherapy achieves high disease-free survival of more than 80 percent in BCG-unresponsive, high-risk papillary NMIBC

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First results from SunRISe-1 (Cohort 4) show strong disease-free survival rates across high-grade papillary tumors, demonstrating the potential for bladder preservation with 94 percent of patients avoiding radical cystectomy

95 percent progression-free survival rate at 9-months signals the promise of TAR-200 in this high-risk patient population

LAS VEGAS, April 26, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced first results from Cohort 4 of the Phase 2b SunRISe-1 study evaluating TAR-200—an intravesical gemcitabine releasing system—for patients with certain types of bladder cancer. These first results show the promise of TAR-200 in this patient population with more than an 80 percent disease-free survival (DFS) rate without the need for reinduction and 94 percent of patients able to preserve their bladder. The high DFS and bladder preservation rate combined with the well-tolerated safety profile in these patients with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non-muscle-invasive bladder cancer (HR-NMIBC) with papillary-only disease (high-grade Ta or T1) show the potential of TAR-200 as a meaningful alternative to surgery. These results were featured in the Paradigm-Shifting, Practice-Changing Clinical Trials in Urology plenary session at the **2025 American Urological Association (AUA) Annual Meeting**.[1]

"The majority of patients remained free of cancer recurrence during this critical early study period, highlighting the potential of TAR-200 as a highly effective treatment for these patients who may have limited options beyond bladder removal," said Félix Guerrero-Ramos*, M.D., PhD, FEBU, Head of Uro-Oncology at Hospital Universitario 12 de Octubre, Madrid, Spain and presenting author. "As we continue monitoring patients through the 12-month mark and beyond, our focus remains on assessing TAR-200's long-term efficacy in maintaining disease-

free survival and improving outcomes for this high-risk patient population."

"Surgical removal of the bladder has long been the standard of care for patients suffering from BCG-unresponsive HR-NMIBC with papillary-only disease, a life-altering procedure that drastically impacts a patient's quality of life," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Johnson & Johnson Innovative Medicine. "These results demonstrate that TAR-200 can be a meaningful alternative to surgery that is both effective and well-tolerated while preserving the bladder."

First results of this interim analysis from Cohort 4 of the SunRISe-1 study demonstrated 85.3 percent and 81.1 percent DFS rates at six and nine months, respectively, in patients with BCG-unresponsive, HR-NMIBC with papillary-only disease treated with TAR-200 monotherapy. These high DFS rates are particularly encouraging given the significant risk of recurrence in this population.[2] Among patients with high-grade Ta and T1 disease, DFS rates remained consistently strong—85.7 percent and 84.7 percent at six months, and 82.1 percent and 79.4 percent at nine months, respectively. The strong DFS across both subtypes—despite their differing depths of invasion—underscores the potential of TAR-200 to deliver sustained tissue penetration. Notably, 94.2 percent of patients avoided radical cystectomy at median follow-up of 12.8 months. The early progression-free and overall survival rates of 95.6 percent and 98 percent at nine months, respectively, are reassuring as disease progression or death were highly uncommon among patients treated with TAR-200.[1] While 12-month DFS data is not yet mature, these preliminary findings show that TAR-200's sustained intravesical gemcitabine delivery may potentially offer durable disease control while minimizing the need for invasive procedures. These results support continued evaluation in the ongoing Phase 3 SunRISe-5 study (**NCT06211764**), comparing TAR-200 to chemotherapy in patients with BCG-pretreated, papillary-only HR-NMIBC.

Among the 52 patients enrolled, the safety profile of TAR-200 monotherapy was consistent with prior studies, with no new safety signals observed. Most treatment-related adverse events (TRAEs) were low grade and resolved quickly, with a median duration of 3.7 weeks. Common TRAEs included dysuria (40.4 percent), pollakiuria (30.8 percent), and urgency (26.9 percent). Grade ≥3 TRAEs occurred in 13.5 percent of patients, most frequently bladder pain (3.8 percent). Three patients (5.8 percent) experienced serious TRAEs, and only four (7.7 percent) discontinued treatment due to TRAEs. No treatment-related deaths were reported.[1]

Bladder cancer ranks among the top ten most common cancers worldwide, affecting nearly a million people each year.[3] Despite advancements, the standard of care has remained largely unchanged for over 40 years, leaving patients with limited treatment options if initial BCG therapy does not work.[4] TAR-200 delivers sustained medication directly into the bladder, offering a fresh approach to treat early-stage bladder cancer.

TAR-200 is inserted directly into the bladder by a healthcare professional in a brief outpatient procedure, without the need for anesthesia. Designed to remain in the bladder, it does not interfere with daily activities and provides

sustained release of treatment throughout the day. To date, TAR-200 has been placed more than 10,000 times as part of the SunRISe clinical program.

About TAR-200

TAR-200 is an investigational intravesical gemcitabine releasing system. In January 2025, Johnson & Johnson announced the initiation of a **new drug application** with the FDA for TAR-200 under the real-time oncology review (RTOR) program. In December 2023, the FDA **granted** Breakthrough Therapy Designation (BTD) to TAR-200 for the treatment of adult patients with BCG-unresponsive HR-NMIBC with CIS who are ineligible for or have elected not to undergo radical cystectomy. The safety and efficacy of TAR-200 are being evaluated in Phase 2 and Phase 3 studies in patients with MIBC in **SunRISe-4**, and NMIBC in **SunRISe-1**, **SunRISe-3** and **SunRISe-5**.

About SunRISe-1, Cohort 4

SunRISe-1 (**NCT04640623**) is an ongoing Phase 2b, randomized, open-label, multicenter study evaluating the efficacy and safety of TAR-200, an intravesical gemcitabine releasing system, in patients with BCG-unresponsive HR-NMIBC who are ineligible for, or elected not to undergo, radical cystectomy. Cohort 4 specifically enrolls patients with papillary-only disease, treating them with TAR-200 monotherapy. The primary end-point of Cohort 4 is disease-free survival (DFS) rate at 12 months. Key secondary end points included safety and tolerability.

About High-Risk Non-Muscle-Invasive Bladder Cancer

High-risk non-muscle-invasive bladder cancer 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 muscle 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.[7] 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.[8,9] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.[10] The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[3,6]

About Johnson & Johnson

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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-200. 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-Cilag International NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC, Janssen-Cilag, S.A., Janssen Scientific Affairs, 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 most recent Annual Report on Form 10-K, 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 **http://www.sec.gov**, **http://www.jnj.com**, or on request from

Johnson & Johnson. None of Janssen-Cilag International NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC, Janssen-Cilag, S.A., Janssen Scientific Affairs, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

*Dr. Guerrero-Ramos has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

[1] Guerrero-Ramos, F., et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin–unresponsive papillary disease–only high-risk non–muscle-invasive bladder cancer: first results from Cohort 4 of SunRISe-1. 2025 American Urological Association Annual Meeting. April 26, 2025.

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