

NEWS RELEASE

# Johnson & Johnson's TAR-200 monotherapy demonstrates highest complete response rate with sustained clinical benefits in patients with certain types of bladder cancer

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Phase 2b SunRISe-1 study shows more than 82 percent of patients achieved complete response (CR) with more than half of responders remaining cancer-free at one year after CR

Results reinforce potential of TAR-200 to transform outcomes for certain types of BCG-unresponsive, high-risk non-muscle invasive bladder cancer

LAS VEGAS, April 26, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from Cohort 2 of the pivotal Phase 2b SunRISe-1 study evaluating TAR-200—an intravesical gemcitabine releasing system—for patients with certain types of bladder cancer. The findings demonstrate the highest complete response rate without reinduction with more than half of responders remaining cancer-free for at least 12 months. These results highlight the potential of TAR-200 as a breakthrough for people with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non-muscle-invasive bladder cancer (HR-NMIBC) with carcinoma in situ (CIS), with or without papillary tumors who are ineligible or refuse radical cystectomy (RC). 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**.<sup>1</sup>

"Treatment with TAR-200 has long-lasting effectiveness. More than 82 percent of patients achieved a complete response, and of those that initially responded to treatment, more than half showed no signs of cancer at one year," said Joseph Jacob\*, M.D., MCR, Associate Professor of Urology at Upstate Medical University and presenting author. "These findings represent the highest complete response rate observed for patients with HR-NMIBC and

underscore the potential of TAR-200 to provide long-lasting cancer control for patients."

"Bladder cancer is one of the ten most common cancers worldwide, yet treatment options have remained largely unchanged for over 40 years, leaving patients with few choices if initial BCG therapy does not work," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Johnson & Johnson Innovative Medicine. "TAR-200 is designed to allow for sustained delivery of medication directly into the bladder through a brief and routine procedure, which benefits patients. These data now show patients can remain cancer-free for a meaningful period of time, marking a significant step forward for those facing this challenging disease."

As of March 2025, 82.4 percent of the 85 enrolled patients in the study achieved a complete response (CR) (95 percent confidence interval [CI], 72.6-89.8), meaning their cancer was undetectable following treatment. This high response rate translated into sustained disease control, with 52.9 percent of responders maintaining complete response at one year. The median duration of response (DOR) was 25.8 months (95 percent CI, 8.3-not estimable), indicating that many patients remained cancer-free for over two years without the need for reinduction therapy. At 12 months, 86.6 percent (95 percent CI, 76.6-92.6) of responders remained cystectomy-free. Importantly, the treatment was well-tolerated, with most adverse events being mild urinary symptoms. These findings show that TAR-200 offers a highly effective and durable treatment option for patients with certain types of BCG-unresponsive HR-NMIBC.

Most treatment-related adverse events (TRAEs) were mild and manageable. Overall, 71 patients (83.5 percent) experienced TRAEs, the majority of which were low-grade urinary symptoms, such as bladder irritation or discomfort. Eleven patients (12.9 percent) experienced Grade 3 or higher TRAEs, and five patients (5.9 percent) reported serious TRAEs. Only three patients (3.5 percent) discontinued treatment due to TRAEs, and there were no treatment-related deaths.

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.

Earlier results from Cohort 2 were previously presented at the **2024 European Society of Medical Oncology (ESMO) Congress** and at the **2024 American Urological Association (AUA) Annual Meeting**. 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.

## 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 2

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 2 specifically enrolls patients with carcinoma in situ, with or without papillary disease, treating them with TAR-200 monotherapy. The primary endpoint for Cohort 2 is CR rate at any time point. Secondary endpoints include duration of response (DOR), overall survival (OS), pharmacokinetics, quality of life, 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.<sup>2,3</sup> 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.<sup>4</sup> 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.<sup>5,6</sup> Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.<sup>7</sup>

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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.innovativemedicine.jnj.com](https://www.innovativemedicine.jnj.com). Follow us at @JNJInnovMed. Janssen-Cilag International NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC, Janssen-Cilag, S.A. and Janssen Scientific Affairs, 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. 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. Jacob has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

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- <sup>1</sup> Jacob, J., et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin-unresponsive high-risk non-muscle-invasive bladder cancer carcinoma in situ: 1-year durability and patient-reported outcomes from SunRISe-1. 2025 American Urological Association Annual Meeting. April 26, 2025.
  - <sup>2</sup> 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.
  - <sup>3</sup> Lieblich A, Henne C, Mariappan P, Geiges G, Pöhlmann J, Pollock RF. The management of non-muscle-invasive bladder cancer: a comparison of European and UK guidelines. *J Clin Urol.* 2018;11(2):144-148.
  - <sup>4</sup> Babjuk M, Burger M, Capoun O, et al. European Association of Urology Guidelines on Non-muscle-invasive Bladder Cancer (Ta, T1, and Carcinoma in Situ). *Eur Urol.* 2022;81(1):75-94. doi:10.1016/j.eururo.2021.08.010
  - <sup>5</sup> 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
  - <sup>6</sup> Guancial EA, Roussel B, Bergsma DP, et al. Bladder cancer in the elderly patient: challenges and solutions. *Clin Interv Aging.* 2015;10:939-949.
  - <sup>7</sup> Chamie K, Litwin MS, Bassett JC, et al. Recurrence of high-risk bladder cancer: A population-based analysis. *Cancer.* 2013;119(17):3219-3227.

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