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NEWS RELEASE

Johnson & Johnson receives U.S. FDA Priority Review for TAR-200 NDA in high-risk non-muscle invasive bladder cancer

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New Drug Application supported by results from the Phase 2b SunRISe-1 study

RARITAN, N.J., July 17, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) granted Priority Review to the New Drug Application (NDA) filed for TAR-200, an intravesical gemcitabine releasing system, for the treatment of patients 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.

"TAR-200 represents an innovation in drug delivery that has not been seen in decades," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "The FDA Priority Review for TAR-200 underscores our mission to fundamentally change the way urologists treat certain types of bladder cancer."

The regulatory submission is supported by data from the Phase 2b SunRISe-1 study, which demonstrated an 82.4 percent complete response (CR) rate with 52.9 percent of patients remaining cancer-free at least one year or more after achievement of a CR (95 percent confidence interval [CI], 72.6-89.8). The majority of adverse reactions were mild and moderate. The most common adverse reactions (≥10 percent) included pollakiuria, dysuria, urinary tract infection, micturition urgency, hematuria, cystitis noninfective, and urinary tract pain. No systemic adverse reactions were reported. The findings were **presented** during a plenary session at the April 2025 American Urological Association Annual Meeting.[1]

Despite advancements, there has been little change in the standard of care for patients with HR-NMIBC for over 40 years, and patients have limited treatment options if initial BCG therapy does not work. TAR-200 is the first and only intravesical drug releasing system (iDRS) designed to provide sustained local delivery of a cancer treatment into the bladder. TAR-200 remains in the bladder for three weeks per treatment cycle.[1] A healthcare professional places it into the bladder using a co-packaged urinary placement catheter in an outpatient setting in less than five minutes. There is no need for general anesthesia, further monitoring, or other restrictions immediately post-insertion within the healthcare provider's office.

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 NMIBC in **SunRISe-1**, **SunRISe-3** and **SunRISe-5** and muscle-invasive bladder cancer (MIBC) in **SunRISe-4**.

About SunRISe-1, Cohort 2

SunRISe-1 (**NCT04640623**), Cohort 2, is a single arm, open-label Phase 2b clinical study evaluating the safety and efficacy of TAR-200 monotherapy for BCG-unresponsive HR-NMIBC patients with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for, or elected not to undergo, radical cystectomy. The primary endpoint for Cohort 2 is complete response (CR) rate at any time point, and secondary endpoints include duration of response (DOR), safety, overall survival and quality of life.

About High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)

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 muscle invasive bladder cancer compared to low-risk NMIBC.[2,3] HR-NMIBC is characterized by a high-grade, large tumor size, presence of multiple tumors, and carcinoma in situ (CIS). HR-NMIBC with CIS makes up approximately 10 percent of patients with NMIBC.[4] Bacillus Calmette-Guérin (BCG), is an intravesical medication administered directly into the bladder that patients have to hold for a few hours.[5,6] BCG is a weakened form of the bacteria found in tuberculosis treatment, and though effective, some patients become unresponsive to it and experience tolerability challenges.[7] Radical cystectomy is currently recommended for HR-NMIBC patients who fail BCG therapy; it is a life-altering surgery with a high degree of morbidity and impact on life, and has a post-surgery mortality rate of three to eight percent.[8,9] Given that HR-NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.

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.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.

[1] 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.

[2] 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.

[3] 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.

[4] Llano A, Chan A, Kuk C, Kassouf W, Zlotta AR. Carcinoma In Situ (CIS): Is There a Difference in Efficacy between Various BCG Strains? A Comprehensive Review of the Literature. Cancers (Basel). 2024;16(2):245. doi:10.3390/cancers16020245

[5] Jiang S, Redelman-Sidi G. BCG in bladder cancer immunotherapy. Cancers (Basel). 2022;14(13):3073. doi:10.3390/cancers14133073

[6] American Cancer Society. Treating bladder cancer. Accessed June 2025. **https://www.cancer.org/cancer/bladder-cancer/treating.html**

[7] Al Hussein Al Awamlh B, Chang SS. Novel therapies for high-risk non-muscle invasive bladder cancer. Curr Oncol Rep. 25, 83–91 (2023). **doi.org/10.1007/s11912-022-01350-9**

[8] EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5

[9] Marqueen KE, et al. JNCI Cancer Spectr. 2018;2:pky075

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