Johnson&Johnson

NEWS RELEASE

Johnson & Johnson unveils highly anticipated and potential practice-changing data in bladder cancer treatment at AUA

2025-04-21

TAR-200 monotherapy shows highest complete response with sustained benefits in 12-month data from Phase 2b SunRISe-1 study (Cohort 2)

Compelling first results from Cohort 4 of Phase 2b SunRISe-1 study show potential of TAR-200 monotherapy in patients with papillary-only, high-risk non-muscle invasive bladder cancer

RARITAN, N.J., April 21, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that new data from its leading oncology pipeline will be presented at the American Urological Association (AUA) 2025 Annual Meeting, taking place April 26-29 in Las Vegas. Among the highlights are the 12-month duration of response (DOR) data from the Phase 2b Cohort 2 SunRISe-1 study, evaluating TAR-200—an intravesical gemcitabine releasing system—for 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 disease. These findings will be featured in the Practice-changing, Paradigm-shifting Clinical Trials in Urology plenary session on Saturday, April 26.

Bladder cancer ranks among the top ten most common cancers worldwide, affecting nearly a million people each year.[1] Despite advancements, standard treatment has remained largely unchanged for over 40 years, leaving patients with limited treatment options if initial BCG therapy does not work.[2] TAR-200 delivers sustained medication directly into the bladder and, in a pre-clinical setting, has been shown to allow for depth of penetration across bladder tissue layers.[3]

"Patients with bladder cancer need more effective treatment options that are both tolerable and easily

incorporated into everyday practice, especially for those with HR-NMIBC, a highly recurrent disease that often necessitates difficult, life-altering decisions like bladder removal," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. "TAR-200 provides a new approach, with clinical data showing an impressive complete response rate, meaning the cancer was undetectable following treatment. The highly anticipated 12-month duration of response findings from our Cohort 2, SunRISe-1 study further support the potential for patients to remain cancer-free for a clinically meaningful period."

A second plenary presentation will feature first results from Cohort 4 of the Phase 2b SunRISe-1 study evaluating TAR-200 monotherapy in patients with BCG–unresponsive, papillary-only HR-NMIBC. In this patient population, bladder removal remains a standard treatment, but many patients are elderly, have significant comorbidities, or are unwilling to undergo radical surgery, making treatment challenging.[4]

"Patients deserve more than the currently available treatment options. TAR-200 is a groundbreaking therapy for early-stage bladder cancer, designed to deliver a sustained local release of medication directly into the bladder—right where it is needed," said Biljana Naumovic, U.S. President, Oncology, Solid Tumor, Johnson & Johnson Innovative Medicine. "This innovation provides a bladder-sparing treatment option that can meaningfully improve outcomes while integrating seamlessly into any urology practice."

TAR-200 is inserted directly into the bladder by a healthcare professional in a brief outpatient, in-office procedure, without the need for anesthesia. Designed to remain in the bladder, it does not interfere with daily activities and provides sustained release of medication throughout the day. To date, TAR-200 has been placed more than 10,000 times as part of the SunRISe clinical program.

AUA 2025 Presentation Highlights:

- One-year duration of response data from the Phase 2b SunRISe-1 study evaluating TAR-200 monotherapy in patients with BCG–unresponsive, HR-NMIBC plus carcinoma in situ with or without papillary disease (P2 Plenary Presentation).
- First results from Cohort 4 of the Phase 2b SunRISe-1 study evaluating TAR-200 monotherapy in patients with BCG–unresponsive papillary-only HR-NMIBC (P2 Plenary Presentation).
- Trial-in-progress mini-oral presentation from the Phase 3 MoonRISe-1 study evaluating TAR-210, an erdafitinib intravesical drug-releasing system, versus intravesical chemotherapy in patients with fibroblast growth factor receptors (FGFR)-altered intermediate-risk NMIBC (Clinical Trials in Progress Presentation).
- Trial-in-progress presentation from the Phase 3 SunRISe-5 study evaluating TAR-200 compared to intravesical chemotherapy after treatment with BCG in patients with recurrent HR-NMIBC (Clinical Trials in Progress Presentation).
- Real-world time-to-next-treatment and time-to-castration-resistance among patients with metastatic

castration-sensitive prostate cancer using androgen-receptor pathway inhibitors with and without homologous recombination repair alterations (Oral Presentation #25-3830).

A complete list of Johnson & Johnson's sponsored abstracts is available on **JNJ.com**.

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 TAR-210

TAR-210 is an investigational intravesical erdafitinib releasing system. The safety and efficacy of TAR-210 is being evaluated in a Phase 1 study (**NCT05316155**) in patients with muscle-invasive bladder cancer (MIBC) and NMIBC.

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 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, with or without 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 Prostate Cancer

Approximately 300,000 people are diagnosed with prostate cancer each year in the U.S.[11] Up to 40 percent of patients will be classified as high-risk.[12] Despite advancements in treatment, disease recurrence remains substantial; up to 50 percent of patients within ten years of surgery experience recurrence and carry a significant risk of disease progression and death.[13]

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 Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC 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, TAR-210 or BALVERSA® (erdafitinib). 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, 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 **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, Janssen Scientific Affairs, LLC nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

[1] **https://www.wcrf.org/preventing-cancer/cancer-statistics/bladder-cancer-statistics/**

[2] Dobruch J, Oszczudłowski M. Bladder Cancer: Current Challenges and Future Directions. Medicina (Kaunas). 2021;57(8):749. Published 2021 Jul 24. doi:10.3390/medicina57080749

[3] Pradère B., et al. PENELOPE: Tissue penetration of gemcitabine phosphate metabolites following TAR-200 administration versus standard intravesical instillation in minipigs. EAU 2025. March 23, 2025.

[4] Lebacle C, Loriot Y, Irani J. BCG-unresponsive high-grade non-muscle invasive bladder cancer: what does the practicing urologist need to know?. World J Urol. 2021;39(11):4037-4046. doi:10.1007/s00345-021-03666-w

[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.

[6] 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.

[7] 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

[8] 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

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

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

[11] Key statistics for prostate cancer. American Cancer Society. Accessed September 2024. **https://www.cancer.org/cancer/types/prostate-cancer/about/key-statistics.html**

[12] Cooperberg MR, Cowan J, Broering JM, et al. High-risk prostate cancer in the United States, 1990-2007. World J Urol. 2008;26(3):211-218. doi: 10.1007/s00345-008-0250-7.

[13] Napodano G, Ferro M, Sanseverino R. High-risk prostate cancer: A very challenging disease in the field of uro-oncology. Diagnostics (Basel). 2021;11(3):400. doi: 10.3390/diagnostics11030400.

Media contact:
Oncology Media Relations
Oncology_media_relations@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

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

View original content to download multimedia:**https://www.prnewswire.com/news-releases/johnson--johnson-unveils-highly-anticipated-and-potential-practice-changing-data-in-bladder-cancer-treatment-at-aua-302433399.html**

SOURCE Johnson & Johnson