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NEWS RELEASE

Johnson & Johnson's INLEXZO™ (gemcitabine intravesical system) delivers 74 percent disease-free survival at one year in BCG-unresponsive, high-risk, papillary-only NMIBC

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New data from Cohort 4 of the SunRISe-1 study show more than 95 percent of patients remained progression free at one year, with more than 92 percent not undergoing bladder removal

Patients with this type of bladder cancer have limited choices beyond radical cystectomy, highlighting the need for newer therapies for bladder preservation

RARITAN, N.J., Dec. 5, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) announced today that new data from the investigational Cohort 4 of the Phase 2b SunRISe-1 study show treatment with gemcitabine intravesical system resulted in high one-year disease-free survival (DFS), progression-free survival (PFS), and overall survival (OS) rates in patients with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk, papillary-only non-muscle invasive bladder cancer (NMIBC).[1] These data were featured as a late-breaking oral presentation at the Society of Urologic Oncology (SUO) 2025 Annual Meeting and build upon data **presented** at the 2025 American Urological Association (AUA) Annual Meeting.

"The findings are meaningful, as the majority of patients remained free of cancer recurrence at one year despite having papillary tumors that carry a high risk for recurrence and a significant risk of progression to a more aggressive, muscle-invasive stage of disease," said Siamak Daneshmand*, M.D., Professor of Urology, University of Southern California, and presenting author. "Bladder removal has traditionally been the primary path forward for these patients, a life-altering procedure that can have a significant impact on a patient's quality of life."

"At Johnson & Johnson, we are committed to developing innovative treatments for patients with high-risk NMIBC who have few options beyond life-altering surgery," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Johnson & Johnson Innovative Medicine. "Those with papillary-only disease face particularly difficult decisions, as surgical removal of the bladder has long been the standard of care for patients who are unresponsive or resistant to BCG."

Cohort 4 of the Phase 2b SunRISe-1 study focused on 52 patients with papillary-only, high-risk NMIBC whose disease did not respond or stopped responding to BCG therapy and who were ineligible for or declined radical cystectomy. The therapy was administered every three weeks for six months, followed by every 12 weeks for up to an additional 18 months, to evaluate its potential to prevent the recurrence or progression of high-grade papillary tumors.[1] The results support continued evaluation in the ongoing Phase 3 SunRISe-5 study (**NCT06211764**) comparing gemcitabine intravesical system to chemotherapy in patients with previously BCG-treated, papillary-only NMIBC.

At median follow-up of 15.9 months (range, 4-20 months), the one-year DFS rate was 74.3 percent (95 percent confidence interval [CI], 59.2-84.6), meaning nearly three out of four patients remained free from cancer recurrence. Results were similar across patients with high-grade Ta and T1 papillary tumors, 74.8 percent and 74.1 percent, respectively (95 percent CI, 54.3-87.1 and 48.5-88.3). At one year, PFS was 95.6 percent (95 percent CI, 83.5-98.9) and OS was 98 percent (95 percent CI, 86.6-99.7). Notably, 92.3 percent of patients did not undergo radical cystectomy, and median time to cystectomy was not reached. Overall Health Status and Physical Functioning scores were maintained during treatment with gemcitabine intravesical system.[1]

The therapy was generally well-tolerated. Most patients (80.8 percent) experienced treatment-related side effects that were low grade, such as mild urinary symptoms, including burning, frequency, or urgency. More serious side effects (13.5 percent) were uncommon and most often involved bladder pain. A small number of patients (7.7 percent) discontinued treatment due to side effects, and no treatment-related deaths were reported.[1]

About SunRISe-1, Cohort 4

SunRISe-1 (**NCT04640623**) is an ongoing Phase 2b, open-label, multicenter study evaluating the efficacy and safety of gemcitabine intravesical 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. The primary endpoint of Cohort 4 is disease-free survival (DFS) rate at 12 months. Key secondary endpoints included safety and tolerability.[2]

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.[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 carcinoma in situ.[5] Radical cystectomy is currently recommended for HR-NMIBC patients who fail BCG therapy, with over 90 percent cancer-specific survival if performed before muscle-invasive progression.[6,7] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.[8] The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[3,4]

About INLEXZO™ (gemcitabine intravesical system)

INLEXZO™ is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors.

The safety and efficacy of INLEXZO™ is being evaluated in clinical trials in patients with MIBC in **SunRISe-4**, and HR-NMIBC in **SunRISe-1**, **SunRISe-3**, and **SunRISe-5**.

The legal manufacturer for INLEXZO™ is Janssen Biotech, Inc.

INLEXZO™ IMPORTANT SAFETY INFORMATION[9]

CONTRAINDICATIONS

INLEXZO™ is contraindicated in patients with:

- Perforation of the bladder.
- Prior hypersensitivity reactions to gemcitabine or any component of the product.

WARNINGS AND PRECAUTIONS

Risks in Patients with Perforated Bladder

INLEXZO™ may lead to systemic exposure to gemcitabine and to severe adverse reactions if administered to patients with a perforated bladder or to those in whom the integrity of the bladder mucosa has been compromised.

Evaluate the bladder before the intravesical administration of INLEXZO™ and do not administer to patients with a

perforated bladder or mucosal compromise until bladder integrity has been restored.

Risk of Metastatic Bladder Cancer with Delayed Cystectomy

Delaying cystectomy in patients with BCG-unresponsive CIS could lead to development of muscle invasive or metastatic bladder cancer, which can be lethal. The risk of developing muscle invasive or metastatic bladder cancer increases the longer cystectomy is delayed in the presence of persisting CIS.

Of the 83 evaluable patients with BCG-unresponsive CIS treated with INLEXZO™ in Cohort 2 of SunRISe-1, 7 patients (8%) progressed to muscle invasive (T2 or greater) bladder cancer. Three patients (3.5%) had progression determined at the time of cystectomy. The median time between determination of persistent or recurrent CIS or T1 and progression to muscle invasive disease was 94 days.

Magnetic Resonance Imaging (MRI) Safety

INLEXZO™ can only be safely scanned with MRI under certain conditions. Refer to section 5.3 of the USPI for details on conditions.

Embryo-Fetal Toxicity

Based on animal data and its mechanism of action, INLEXZO™ can cause fetal harm when administered to a pregnant woman if systemic exposure occurs. In animal reproduction studies, systemic administration of gemcitabine was teratogenic, embryotoxic, and fetotoxic in mice and rabbits.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after final removal of INLEXZO™. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after final removal of INLEXZO™.

ADVERSE REACTIONS

Serious adverse reactions occurred in 24% of patients receiving INLEXZO™. Serious adverse reactions that occurred in >2% of patients included urinary tract infection, hematuria, pneumonia, and urinary tract pain. Fatal adverse reactions occurred in 1.2% of patients who received INLEXZO™, including cognitive disorder.

The most common (>15%) adverse reactions, including laboratory abnormalities, were urinary frequency, urinary tract infection, dysuria, micturition urgency, decreased hemoglobin, increased lipase, urinary tract pain, decreased

lymphocytes, hematuria, increased creatinine, increased potassium, increased AST, decreased sodium, bladder irritation, and increased ALT.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on the use of INLEXZO™ in pregnant women to inform a drug-associated risk. Please see Embryo-Fetal Toxicity for risk information related to pregnancy.

Lactation

Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment and for 1 week after final removal of INLEXZO™.

Females and Males of Reproductive Potential

Pregnancy Testing - Verify pregnancy status in females of reproductive potential prior to initiating INLEXZO™.

Contraception - Please see Embryo-Fetal Toxicity for information regarding contraception.

Infertility (Males) - Based on animal studies, INLEXZO™ may impair fertility in males of reproductive potential. It is not known whether these effects on fertility are reversible.

Geriatric Use

Of the patients given INLEXZO™ monotherapy in Cohort 2 of SunRISe-1, 72% were 65 years of age or older and 34% were 75 years or older. There were insufficient numbers of patients <65 years of age to determine if these patients respond differently to patients 65 years of age and older.

Please read full **Prescribing Information** and **Instructions for Use** for INLEXZO™.

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**.

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 INLEXZO™. 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 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. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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

[1] Daneshmand, S., & colleagues. (2025). Gemcitabine intravesical system (TAR-200) monotherapy in patients with Bacillus Calmette-Guérin–unresponsive papillary disease–only high-risk non–muscle-invasive bladder cancer: 1-year disease-free survival results from SUNRISE-1. Abstract presented at the Society of Urologic Oncology (SUO) Annual Meeting.

[2] **ClinicalTrials.gov**. 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). **https://clinicaltrials.gov/study/NCT04640623**. Accessed December 2025.

[3] 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.

[4] 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.

[5] 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

[6] 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

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

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

[9] INLEXZO™ U.S. Prescribing Information.

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