Johnson&Johnson

NEWS RELEASE

U.S. FDA approval of INLEXZO™ (gemcitabine intravesical system) set to transform how certain bladder cancers are treated

2025-09-09

First and only drug releasing system to provide extended local delivery of a cancer medication into the bladder, with 82 percent of patients achieving complete response without the need for reinduction[1]

Potential practice-changing treatment for certain patients with BCG-unresponsive non-muscle invasive bladder cancer who have limited options before possible bladder removal

RARITAN, N.J., Sept. 9, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) announced today the U.S. Food and Drug Administration (FDA) approved INLEXZO™ (gemcitabine intravesical system), a new, potentially practice-changing approach for treating patients with certain types of bladder cancer, addressing the need for additional options following unsuccessful BCG therapy and for patients refusing or ineligible for bladder removal surgery (radical cystectomy).[1] INLEXZO™, previously referred to as TAR-200, is indicated 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.[1]

Multimedia assets for media are available **here**.

INLEXZO™ is designed for patients seeking bladder preservation and is the first and only intravesical drug releasing system (iDRS) to provide extended local delivery of a cancer medication into the bladder. INLEXZO™ remains in the bladder for three weeks per treatment cycle for up to 14 cycles.[1] A healthcare professional places INLEXZO™ into the bladder using a co-packaged urinary catheter and stylet to insert it into the bladder.[1] INLEXZO™ is placed in an outpatient setting in a few minutes, without the need for general anesthesia or further monitoring immediately

post-insertion within the healthcare provider's office.[1]

"When we acquired this novel therapy in 2019, our ambition was to give patients with bladder cancer a renewed sense of hope and belief," said Jennifer Taubert, Executive Vice President, Worldwide Chairman, Innovative Medicine, Johnson & Johnson. "In an area that has seen little progress for more than 40 years, INLEXZO delivers a first-of-its-kind breakthrough innovation with a bright future ahead."

The approval is supported by data from the SunRISe-1 (**NCT04640623**) single arm, open-label Phase 2b clinical study.[1] Results show 82 percent of patients with BCG-unresponsive NMIBC treated with INLEXZO™ achieved a complete response (CR), meaning no signs of cancer were found after treatment (95 percent confidence interval [CI], 72, 90).[1] This high response rate demonstrated strong durability, and 51 percent of these patients maintained a complete response for at least one year.[1]

In the SunRISe-1 clinical trial supporting this approval, the most common adverse reactions (≥15 percent) 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 aspartate aminotransferase (AST), decreased sodium, bladder irritation, and increased alanine transaminase (ALT).[1]

"I see many patients that ultimately become BCG-unresponsive and often face life-altering bladder removal. These patients now may be ideal candidates for newly approved INLEXZO," said Sia Daneshmand, M.D., TAR-200 SunRISe-1 principal investigator, and Professor of Urology, Director of Urologic Oncology at the Norris Comprehensive Cancer Center, Keck School of Medicine of University of Southern California.* "In my experience, INLEXZO is well-tolerated and delivers clinically meaningful results. This will change the way we treat appropriate patients that haven't responded to traditional therapy."

"We are proud of the science that has brought us to this historic moment," said John Reed, M.D., Ph.D., Executive Vice President, R&D, Innovative Medicine, Johnson & Johnson. "INLEXZO is a novel therapy with powerful efficacy and demonstrated safety profile. As the only major healthcare company that hosts both pharmaceuticals and medical devices, we leveraged the speed and scale of Johnson & Johnson to accelerate innovation and deliver this important therapy to patients."

"At **BCAN**, our mission has always been to advocate for better todays and more tomorrows for everyone impacted by bladder cancer. This approval represents the kind of progress that brings new options to a community that urgently needs them," said Meri-Margaret Deoudes, CEO, Bladder Cancer Advocacy Network (BCAN).** "Patients with bladder cancer need guidance and collaboration with providers to navigate bladder-

sparing treatment options, including newly approved treatments like INLEXZO, so they can move forward feeling well-informed and confident."

Leading to today's approval, the FDA granted INLEXZO™ **Breakthrough Therapy Designation** (BTD), **Real-Time Oncology Review** (RTOR), and **Priority Review**.

Johnson & Johnson is committed to helping patients access our treatments. Once a patient and their doctor have decided that INLEXZO™ is right for the patient, **J&J withMe** provides a simple, comprehensive patient support program offering cost support, a dedicated Care Navigator and educational resources, at no cost to the patient.

About SunRISe-1, Cohort 2

SunRISe-1 (**NCT04640623**), Cohort 2, was a single arm, open-label Phase 2b clinical study that evaluated the safety and efficacy of INLEXZO™ monotherapy for BCG-unresponsive 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 was complete response (CR) rate at any time point, and secondary endpoints include duration of response (DOR).

About Non-Muscle Invasive Bladder Cancer (NMIBC) and the Current Standard of Care

Non-muscle invasive bladder cancer (NMIBC) is a type of non-invasive bladder cancer that can be classified as low, intermediate, or high risk depending on the presence of characteristics including tumor size, presence of multiple tumors, and carcinoma in situ (CIS).[2] NMIBC with CIS makes up approximately 10 percent of patients with NMIBC.[3] The current standard of care for NMIBC is Bacillus Calmette-Guérin (BCG), which is a weakened form of the bacteria found in tuberculosis treatment. Though effective, some patients become unresponsive to it and may experience challenges.[4,5] Radical cystectomy is currently recommended for NMIBC patients who fail BCG therapy; it is a life-altering surgery with a high degree of morbidity and adverse impact on life, and has a post-surgery mortality rate of three to eight percent.[6,7] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.

About INLEXZO™

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. INLEXZO™ is an intravesical system enabling extended release of gemcitabine into the bladder. It is placed in a few minutes without general anesthesia or further monitoring immediately post-insertion within the healthcare provider's office. For more information, visit **INLEXZO.com**.

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

INLEXZO™ INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

INLEXZO™ (gemcitabine intravesical system) is indicated 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.

IMPORTANT SAFETY INFORMATION

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™.

cp-520096v1

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**. Janssen Research & Development, LLC, and Janssen Biotech, Inc., 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 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 **www.sec.gov**, **www.jnj.com** or on request from Johnson & Johnson. Johnson

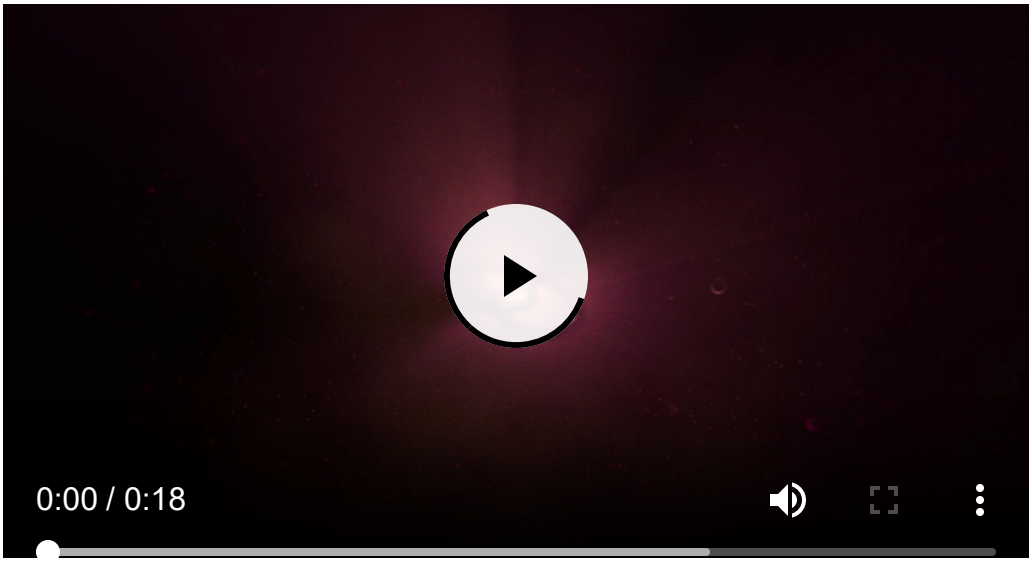
& Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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

References

INLEXZO™ U.S. Prescribing Information.
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. doi:10.3389/fonc.2023.1170124
Llano A, Chan A, Kuk C, et al. 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
Jiang S, Redelman-Sidi G. BCG in bladder cancer immunotherapy. Cancers (Basel). 2022;14(13):3073. doi:10.3390/cancers14133073
Al Hussein Al Awamlh B, Chang SS. Novel therapies for high-risk non-muscle invasive bladder cancer. Curr Oncol Rep. 2023;25(2):83-91. doi:10.1007/s11912-022-01350-9
Aminoltejari K, Black PC. Radical cystectomy: a review of techniques, developments and controversies. Transl Androl Urol. 2020;9(6):3073-3081. doi:10.21037/tau.2020.03.23
Marqueen KE, Waingankar N, Sfakianos JP, et al. Early mortality in patients with muscle-invasive bladder cancer undergoing cystectomy in the United States. JNCI Cancer Spectr. 2018;2(4):pky075. doi:10.1093/jncics/pky075

cp-523390v1



View original content:**https://www.prnewswire.com/news-releases/us-fda-approval-of-inlexzo-gemcitabine-intravesical-system-set-to-transform-how-certain-bladder-cancers-are-treated-302551487.html**

SOURCE Johnson & Johnson