

Inlexzo: a potentially paradigm-shifting therapy in non-muscle-invasive bladder cancer

Market Event Summary

Event

- **Inlexzo secured FDA approval on September 9, 2025**, providing a new, potentially practice-changing therapy for bacillus Calmette-Guérin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC). It is a transformative advance for difficult-to-treat disease.
- **The pivotal single-arm cohort 2 of Phase 2b SunRISe-1 trial (n=83)** assessed Inlexzo in patients with BCG-unresponsive high-risk NMIBC with carcinoma in situ (CIS), with or without papillary tumors, who were ineligible for or who elected not to undergo radical cystectomy. It demonstrated:
 - **More than 80% of patients** treated with Inlexzo achieved a **complete response (CR)**.
 - **51% of patients** maintained a CR for at least one year, demonstrating strong **durability**.
 - The **12- and 24-month radical cystectomy-free rates** for Inlexzo were **86% and 75%**, respectively, indicating significant bladder-sparing potential.
 - Inlexzo **was well tolerated** and displayed a low treatment **discontinuation rate** due to adverse events **of 5.9%**.

Background

- **Radical cystectomy** is the standard of care for BCG-unresponsive NMIBC.
- **Before approval of Inlexzo**, BCG-unresponsive NMIBC patients who are ineligible for or who refuse radical cystectomy had limited treatment options, including Keytruda, Adstiladrin, and Anktiva.
- **A major unmet need** existed for additional bladder-sparing treatment options for patients who become unresponsive to BCG treatment.
- **Inlexzo** (previously called TAR-200) is an **intravesical drug-releasing system** that releases gemcitabine directly into the bladder.



Clarivate's takeaways



Most lucrative bladder cancer patient population

75% of newly diagnosed bladder cancer patients have NMIBC, and about 10% of these cases involve CIS. The non-muscle-invasive segment is the largest patient group in the U.S. bladder cancer, accounting for 58% of total drug-treatable opportunities in 2024. NMIBC is typically diagnosed in older adults, and a sizeable proportion of patients refuse or are unfit for radical cystectomy after failing BCG therapy.



Ease of delivery could be a key differentiator

Inlexzo is an intravesical drug delivery system installed by an HCP within minutes in an outpatient setting, without general anesthesia and further monitoring.



Poised to achieve blockbuster status

With the best efficacy data in NMIBC, Inlexzo will soon achieve blockbuster sales. J&J has a comprehensive clinical studies program across different bladder cancer populations to maximize Inlexzo's potential.

About the author



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Dr. Walker has more than 12 years' experience in the pharmaceutical field. She has authored thought-leadership articles covering a broad range of pharmaceutical-industry-relevant topics and therapeutic areas, including the flagship Drugs to Watch article. She holds a Ph.D. in cell biology and genetics from the University of Manchester and was a Wellcome postdoctoral fellow at the University College London Institute of Healthy Ageing.



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Dr. Bhatt combines a decade of academic research with industry experience to deliver actionable insights in oncology. Prior to joining Clarivate, she worked as a Solution Scientist at Merck Life Science Pvt. Ltd., where she spearheaded strategic collaborations, provided tailored scientific solutions, and conducted market assessments for various biopharma clients. She holds a Ph.D. in Cellular and Molecular Immunology and an M.Sc. in Molecular Biology from the Max Planck Research School in Germany, where her research focused on studying the signaling pathways downstream of the B Cell antigen receptor.

Clarivate coverage of bladder cancer and upper tract urothelial carcinoma

- Bladder cancer and upper tract urothelial carcinoma [Disease Landscape & Forecast \(G7\)](#).
- Bladder cancer and upper tract urothelial carcinoma [Current Treatment: Physician Insights: US](#) - explores the current prescribing trends of medical oncologists treating bladder cancer and upper tract urothelial carcinoma.
- Bladder cancer and upper tract urothelial carcinoma [Current Treatment: Treatment Sequencing: US](#) - presents surveyed medical oncologists' most frequent treatment sequences for bladder cancer and upper tract urothelial carcinoma.
- Unresectable locally advanced or metastatic bladder cancer- [Detailed, Expanded Analysis](#) on Unresectable locally advanced or metastatic bladder cancer.



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