INLEXZO™ (TAR200)

The anatomy of a Drug to Watch

Key evaluation criteria in bladder cancer and how INLEXZO was selected as a Drug to Watch 2026

Clarivate analysts rely on actionable data and market intelligence from our suite of products to identify each year's Drugs to Watch — the blockbusters and treatment paradigm-shifters.

Identifying the next breakthroughs for bladder cancer

A crowded therapeutic landscape creates uncertainty in bladder cancer treatment sequencing, making it difficult to predict which therapies will establish durable clinical positioning as biomarker strategies and resistance patterns evolve. To identify the breakthroughs, the first step is translating the evidence base into a clear view of which drugs are likely to launch and succeed within the 'Drugs to Watch' target timeframe.

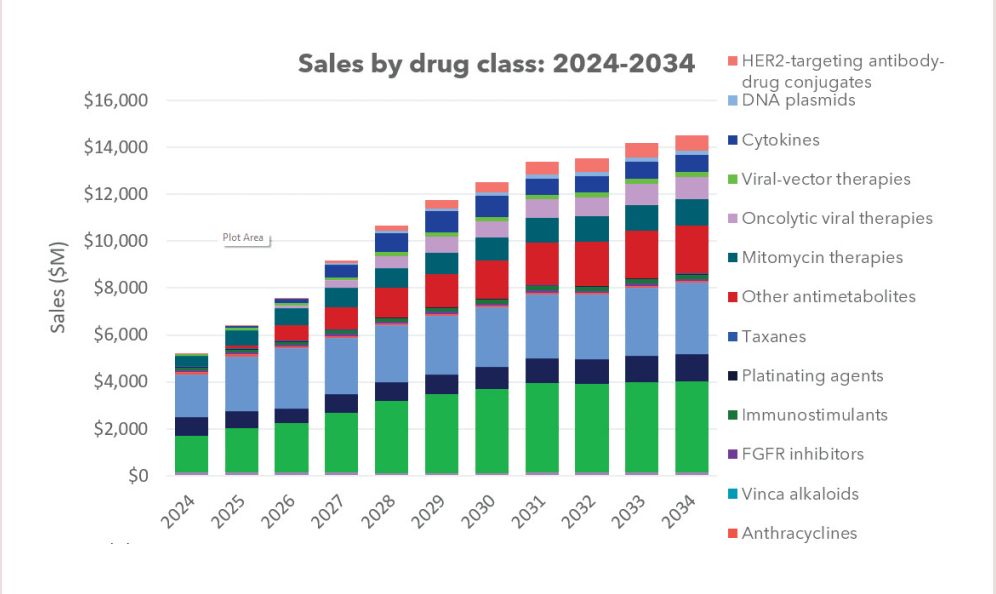
Mapping the therapeutic landscape: Disease Landscape & Forecast

Our analysts gain a broad view of the status and potential success of drugs for bladder cancer using Disease Landscape & Forecast, which provides access to:

- World-class epidemiology, KOL insights and therapy area expert opinions
- 10-year, epidemiology-based sales, patient share and other proprietary forecasts tailored for each disease area
- Data updates based on regulatory, clinical and market events

By reviewing the therapeutic landscape, Clarivate analysts narrow the field to a short list of assets that warrant deeper investigation as Drugs to Watch, such as INLEXZO™ (TAR200; intravesical gemcitabine delivery system) in bladder cancer.

Figure 1: Sales by drug class within the NMIBC population from Disease Landscape & Forecast



INLEXZO

Device-enabled delivery with bladder-sparing efficacy

Disease Landscape & Forecast

Shows how INLEXZO offers a bladder-sparing alternative within an evolving treatment landscape in non-muscle invasive bladder cancer (NMIBC), where patients face limited options following BCG failure.

- ~270k new drug treatable NMIBC cases in the G7 markets in 2025, with a BCG-unresponsive subset historically funneled toward radical cystectomy
- Forecast to reach ~$1.80bn in G7 market sales by 2031, driven initially by BCG-unresponsive high-risk NMIBC (HR-NMIBC) then expanded use in BCG-naive and papillary-only disease as SunRISe data mature
- PD-1/PDL-1 inhibitor sales in NMIBC forecast to reach ~$2bn by 2033; INLEXZO's bladder-sparing approach and efficacy likely to enable differentiation across immunotherapy-treated populations and other pharmacologic bladder-sparing options

Learn more

Cortellis Clinical Trials Intelligence

Indicates how a high complete response (CR) rate, long duration of response (DOR) and cystectomy preservation in BCG-unresponsive HR-NMIBC patients support positioning INLEXZO as a compelling bladder-sparing option.

- Phase 2b SunRISe1 trial (200 patients with BCG-unresponsive HR-NMIBC [CIS ± papillary]):
  - INLEXZO monotherapy: 82.4% CR, median DOR 25.8 months, 52.9% 12-month DOR rate, 86.6% 12-month radical cystectomy-free rate, 98.7% and 94.7% 6- and 12-month overall survival (OS) rates, respectively
  - INLEXZO + cetrelimab: 67.9% CR, median DOR not estimable, 76.3% 12-month DOR rate, 98% 12-month OS rate
  - Cetrelimab monotherapy: 46.4% CR, median DOR 8.6 months, 38.5% 12-month DOR rate
- Ongoing phase 2/3 SunRISe-3, -4 and -5 trials extending use into BCG-naive HR-NMIBC, MIBC and recurrent papillary-only disease, targeting earlier and broader disease stages

Learn more

Epidemiology Intelligence

Highlights how a low-touch, sustained-release intravesical device offers a realistic path to disease control without bladder loss for surgery-averse patients.

- NMIBC predominantly affecting older patients, many of whom may be medically unfit or decline radical cystectomy because of morbidity and quality-of-life impact
- Standard BCG therapy in HR-NMIBC requiring repeated intravesical instillations with prolonged monitored dwell times, creating logistical and tolerability burdens, especially amid global BCG shortages
- <5 minutes required for INLEXZO insertion in an outpatient setting without general anesthesia; device remains in situ for ~3 weeks, reducing hospital visits and observation time

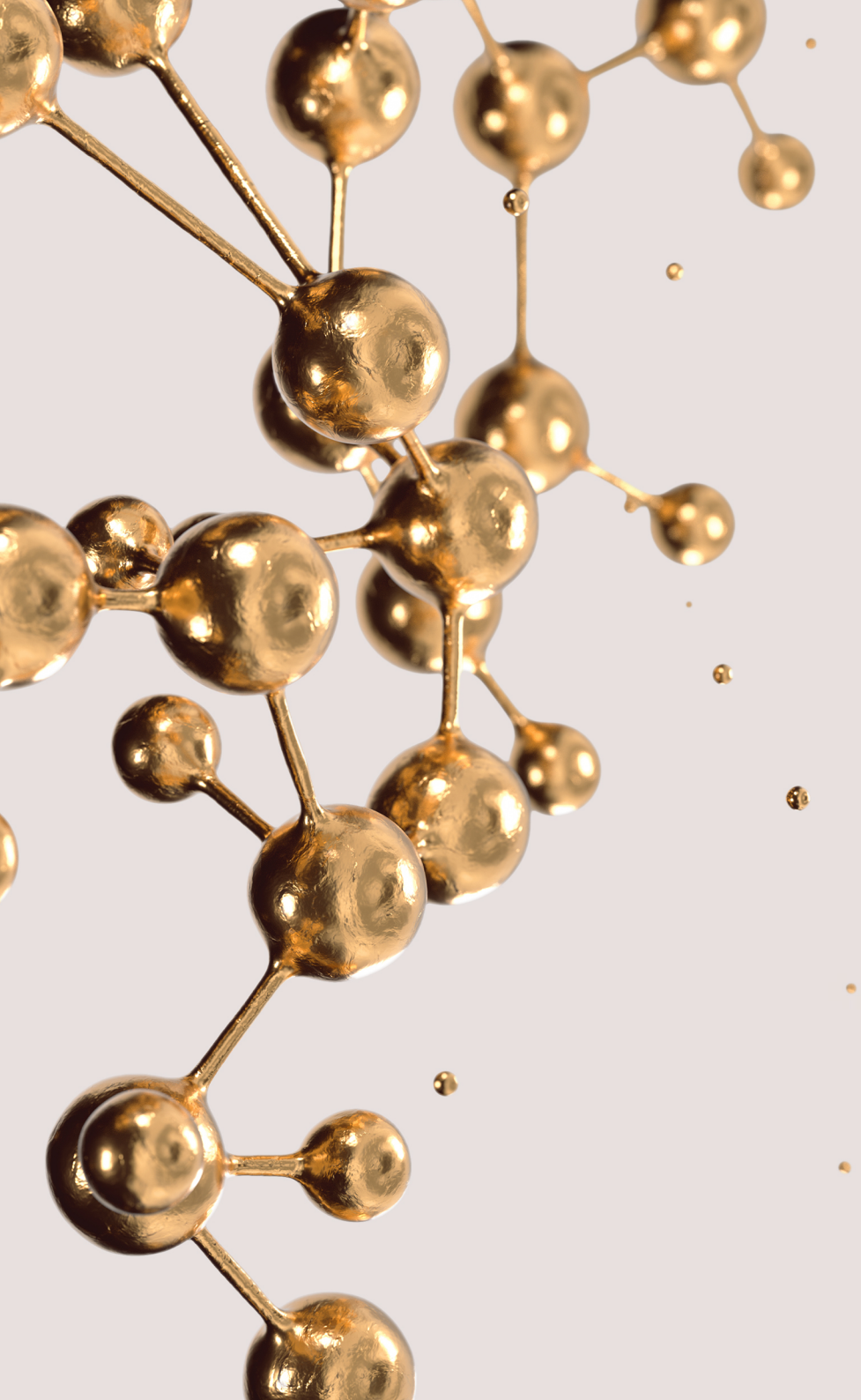
Learn more

DRG Fusion (Real-World Evidence & Market Access)

Indicates how bladder preservation and reduced treatment frequency support a compelling cost–utility profile, particularly in high-risk, aging populations.

- Reduced frequency of intravesical administrations with INLEXZO's extended-release dosing schedule (every 3 weeks for up to 6 months, followed by maintenance every 12 weeks) compared with weekly BCG instillations and post-procedure monitoring
- Potential to delay progression to radical cystectomy, reduce inpatient stays and preserve quality of life as key value drivers for payers, according to health-economic models
- Real-world data critical to confirm durability and safety observed in the SunRISe-1 trial across broader clinical practice settings and to support expansion into BCG-naive and papillary-only populations

Learn more



Summary of impact

INLEXZO

INLEXZO is poised to redefine bladder-sparing care in BCG-unresponsive NMIBC by transforming delivery into a competitive advantage. Sustained-release intravesical gemcitabine demonstrates the potential for durable local control without systemic burden or radical surgery, positioning INLEXZO to capture share from both checkpoint inhibitors and cystectomy pathways while validating device-drug platforms as a route to premium oncology positioning.

Ready to see if your drug is one to watch?

Contact us to learn how integrating intelligence from multiple Clarivate products, powered by AI, drives confident predictions of the potential competitive impact of your drug on the market and patients' lives.

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