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NEWS RELEASE

# Johnson & Johnson highlights promising first-in-human Erda-iDRS (formerly TAR-210) results in intermediate-risk non-muscle-invasive bladder cancer

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- Data presented at EAU 2026 show an 89 percent complete response rate in intermediate-risk disease with durable responses observed over 18 months and tolerable safety profile
- Erda-iDRS has the potential to be the first targeted treatment for early–stage bladder cancer

RARITAN, N.J., March 13, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) today announced results from an open-label, multicenter Phase 1 study evaluating an investigational intravesical drug-releasing system with erdafitinib (Erda-iDRS) in patients with intermediate-risk and high-risk non–muscle-invasive bladder cancer (NMIBC) whose tumors harbor select fibroblast growth factor receptor (FGFR) alterations. The study met its primary safety endpoint and demonstrated complete and durable responses in patients with recurrent intermediate-risk disease, along with encouraging recurrence-free outcomes in high-risk disease. These findings support continued development of this targeted approach with ongoing Phase 2 and Phase 3 studies evaluating Erda-iDRS across risk settings. Data were presented during a late-breaking oral session at the European Association of Urology (EAU) 2026 Annual Meeting (Abstract #LB26-0083).[1]

FGFR alterations are common in early-stage bladder cancer, occurring in approximately 70 percent of intermediate-risk and 40 percent of high-risk non–muscle-invasive bladder cancer tumors.[2,3] Because these changes may drive tumor growth, they represent an important therapeutic target in this setting. Erda-iDRS is designed to provide prolonged release of erdafitinib, an oral kinase inhibitor, directly into the bladder via intravesical administration over a three-month period, and may enable localized treatment while aiming to minimize systemic exposure and the risk of adverse events associated with oral administration.

"Intermediate-risk non–muscle-invasive bladder cancer is defined by recurrences, and many patients undergo repeated procedures as their tumors return," said Antoni Vilaseca Cabo,* M.D., adjunct physician of the Urology Service at Hospital Clínic de Barcelona in Spain, and presenting author. "In this study, treatment with Erda-iDRS led most patients with FGFR-altered disease to achieve a complete response by the end of the second treatment cycle, and many of those responses were sustained over time. Achieving and maintaining a complete response is particularly meaningful in this setting, where recurrence is common and requires repeated surgical intervention."

"For patients with FGFR-altered non–muscle-invasive bladder cancer, care has historically not been guided by precision-based approaches," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Johnson & Johnson. "The high and durable complete responses demonstrated with Erda-iDRS highlight the opportunity to deliver a targeted therapy to these patients. Bringing a biology-based approach into earlier stages of this disease has the potential to change how these patients are treated."

## Detailed Study Results

In this Phase 1 study, Erda-iDRS was evaluated in patients with non–muscle-invasive bladder cancer harboring select FGFR alterations identified by urine and/or tissue testing. As of November 3, 2025, 62 patients with recurrent intermediate-risk non–muscle-invasive bladder cancer and 26 patients with recurrent, Bacillus Calmette-Guérin (BCG)-experienced, high-risk non–muscle-invasive bladder cancer had received treatment. The primary endpoint was safety, with the secondary endpoints assessing complete response rate and duration of CR in the intermediate-risk cohort and recurrence-free survival in the high-risk cohort.[1]

In the intermediate-risk cohort, Erda-iDRS was evaluated as a non-surgical treatment for visible tumors. The complete response rate was 89 percent (95 percent confidence interval [CI], 78-95), based on tumor assessments during the initial treatment period. Among responders, the median duration of complete response was 18 months (95 percent CI, 14-25), with a median follow-up of 18 months (range, 15-21), indicating prolonged responses over time. Forty-nine percent of patients remain in follow-up.[1]

In the high-risk cohort, patients treated with Erda-iDRS had a median recurrence-free survival of 20 months (95 percent CI, 15-30), with a 12-month recurrence-free survival rate of 83 percent (95 percent CI, 62-93). With a median recurrence-free survival follow-up of 24 months (range, 15-30), 31 percent of patients remain in follow-up.[1]

Treatment was generally well tolerated, as evidenced by the absence of dose-limiting toxicities and a safety profile characterized by predominantly local adverse events. In the combined cohorts, the most frequent treatment-related adverse events (TRAEs) were hematuria (32 percent) and dysuria (22 percent). Grade 3 or higher TRAEs occurred in four patients (5 percent). Eight patients (9 percent) discontinued treatment due to adverse events, and two patients (2 percent) experienced serious TRAEs. Pharmacokinetic analyses demonstrated prolonged drug levels

in the urine, with limited systemic exposure and no observed hyperphosphatemia.[1]

## Continued Development

Phase 2 and Phase 3 studies are ongoing to evaluate Erda-iDRS in intermediate- and high-risk non–muscle-invasive bladder cancer. The MoonRISe program includes the Phase 3 MoonRISe-1 study (**NCT06319820**) in intermediate-risk disease in the adjuvant setting (after tumor resection), the Phase 2 MoonRISe-2 study (**NCT05316155**) in intermediate-risk disease in the ablative setting (evaluating treatment of visible tumors without surgery), and the Phase 3 MoonRISe-3 study (**NCT06919965**) in patients with high-risk papillary non–muscle-invasive bladder cancer who received prior BCG therapy, including those with BCG-unresponsive disease, in the adjuvant setting.[4,5,6]

## About Erdafitinib Intravesical Drug-Releasing System (Erda-iDRS)

Erda-iDRS is an investigational intravesical drug delivery system designed to deliver prolonged, localized erdafitinib, an oral kinase inhibitor, directly to the bladder. The safety and efficacy of Erda-iDRS are being evaluated in a Phase 1 study in patients with non–muscle-invasive bladder cancer (NMIBC), including those with high-risk, BCG-unresponsive disease and intermediate-risk disease with visible tumors. Additional Phase 2 and Phase 3 studies are ongoing to further assess Erda-iDRS across intermediate- and high-risk NMIBC.

In 2008, Janssen Pharmaceuticals entered into an exclusive worldwide license and collaboration agreement with Astex Pharmaceuticals to develop and commercialize erdafitinib.

## About Non–Muscle-Invasive Bladder Cancer

Non–muscle-invasive bladder cancer (NMIBC) is an early stage of bladder cancer confined to the lining of the bladder. It accounts for approximately 75 percent of newly diagnosed bladder cancer cases. NMIBC is categorized as low-, intermediate-, or high-risk based on tumor characteristics and likelihood of recurrence or progression.[7]

Patients with intermediate-risk NMIBC experience frequent tumor recurrences that often require repeated procedures and ongoing monitoring. High-risk NMIBC carries a greater likelihood of progression to muscle-invasive disease, which may require radical cystectomy.[8,9,10] Despite available treatments, recurrence and progression remain common across intermediate- and high-risk disease, underscoring the need for durable bladder treatment options.

## About Johnson & Johnson

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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 the intravesical drug-releasing system with erdafitinib (Erda-iDRS). 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.

*Antoni Vilaseca Cabo, M.D., has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

[1] Vilaseca A, et al. Safety and efficacy of the erdafitinib (erda) intravesical delivery system, TAR-210, in patients with non–muscle-invasive bladder cancer (NMIBC) or muscle-invasive bladder cancer (MIBC) harboring select FGFR mutations or fusions: phase 1 first-in-human study. Presented at: 2026 European Association of Urology (EAU); March 13, 2026; London.

[2] Roupret M, et al. Eur Urol. 2022;87(S 1):A0673

[3] Catto JWF, et al. Ann Oncol. 2024;35:98-106

[4] ClinicalTrials.gov. A Study to Evaluate TAR-210 Versus Single Agent Intravesical Cancer Treatment in Participants With Bladder Cancer (MoonRISe-1). **https://clinicaltrials.gov/study/NCT06319820**. Accessed March 2026.

[5] ClinicalTrials.gov. Study of Erdafitinib Intravesical Delivery System for Localized Bladder Cancer. **https://clinicaltrials.gov/study/NCT05316155**. Accessed March 2026.

[6] ClinicalTrials.gov. A Study to Evaluate TAR-210 Versus Intravesical Chemotherapy Treatment in Participants With High Risk Non-Muscle-Invasive Bladder Cancer (MoonRISe-3). **https://clinicaltrials.gov/study/NCT06919965**. Accessed March 2026.

[7] Johnson & Johnson. Bladder cancer. Johnson & Johnson Innovative Medicine. Published June 30, 2025. **https://www.jnj.com/innovativemedicine/oncology/bladder-cancer**. Accessed March 2026.

[8] 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

[9] 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

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

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

Investor contact:
Jess Margevich
**investor-relations@its.jnj.com**

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

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