MoonRISe-2, a Phase 2 Dose Expansion Study of Erdafitinib Intravesical Drug-Releasing System (Erda-iDRS) for Localized Bladder Cancer: Study Design and Baseline Characteristics

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Presented by CM Pieczonka at the 121st AUA Annual Meeting; May 15-18, 2026; Washington, DC, USA

Disclosures

- Dr Pieczonka has received honoraria from Johnson & Johnson/Janssen, Dendreon, Pfizer/Astellas, Bayer, Sun Pharma, Myovant Sciences, Merck, AstraZeneca, Bristol Myers Squibb, and Novartis; consulting/advisory role fees from Pfizer/Astellas, Bayer, Johnson & Johnson/Janssen Oncology, Tolmar, Sun Pharma, Dendreon, AstraZeneca, Merck, Bristol Myers Squibb, and Novartis; research funding from Bayer, Pfizer, Astellas Pharma, Merck, AstraZeneca, Advantagene, Dendreon, Johnson & Johnson/Janssen Oncology, and InVitae; and has served on speaker's bureau for Bayer, Dendreon, Pfizer, Astellas Pharma, Sun Pharma, Myovant Sciences, Johnson & Johnson/Janssen Oncology, AstraZeneca, and Merck

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High Unmet Need Persists in Recurrent IR NMIBC

- Bladder cancer predominantly affects older males who suffer from comorbidities and long-term effects of tobacco use[1]
- Standard of care for IR NMIBC is TURBT followed by adjuvant intravesical therapy (chemotherapy or BCG)[2,3]
- TURBT is associated with procedural risks and complications (eg, bleeding, infection, perforation) and cumulative morbidity (eg, LUTs, UTIs) from repeated procedures in addition to the risks and burden associated with the commonly used anesthesia[4-6]
- Additionally, there remains a high probability of disease recurrence (>60% at 5 years) and progression (up to 17%), particularly in patients with ≥1 IBCG risk factor, despite the use of TURBT ± adjuvant therapy[7,8]
  - Frequent recurrence adds to disease burden, requiring cystoscopic surveillance and repeat interventions[2,3]
- There are currently limited options for durable disease control in IR NMIBC

BCG, bacillus Calmette-Guérin; HR, high-risk; IBCG, International Bladder Cancer Group; IR, intermediate-risk LUTs, lower urinary tract symptoms; NMIBC, non–muscle-invasive bladder cancer; TURBT, transurethral resection of bladder tumor; UTI, urinary tract infection.

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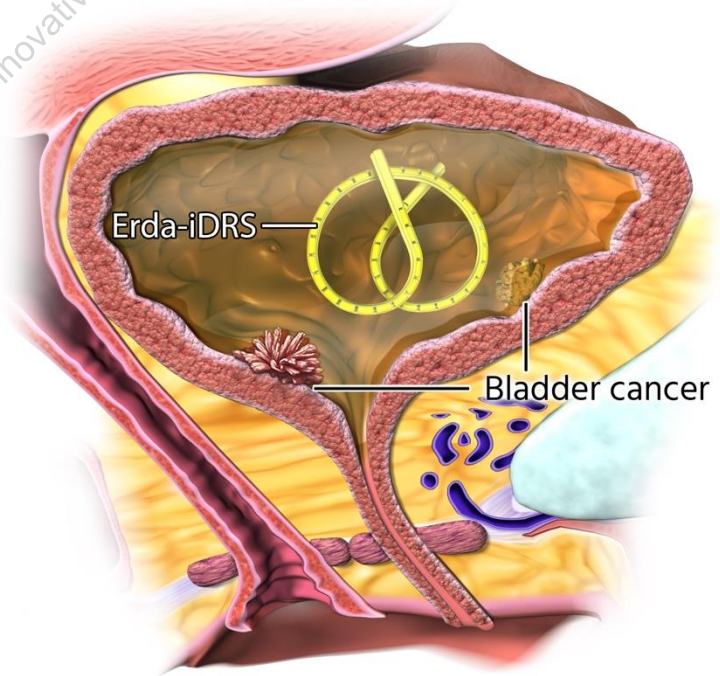
Erda-iDRS for Localized Treatment of *FGFR*-Altered IR NMIBC

- *FGFR* alterations occur in a high proportion (~70%) of IR NMIBC tumors and may function as oncogenic drivers[1,2]
- Erdafitinib is an oral, selective pan-FGFR inhibitor approved to treat susceptible *FGFR3*-altered mUC following progression after prior systemic treatment[3-5]
- In the first-in-human ablative study in patients with *FGFR*-altered IR NMIBC, erda-iDRS was well tolerated and showed a high CR rate (89%), with a median CR duration of 18 months[6]

Erda-iDRS (TAR-210) is an intravesical drug-releasing system designed to provide sustained delivery of erdafitinib to the bladder in 3-month treatment cycles and to limit systemic exposure



Erda-iDRS is inserted using a urinary placement catheter in a brief in-office procedure

CR, complete response; FGFR, fibroblast growth factor receptor; mUC, metastatic urothelial carcinoma.

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MoonRISe-2: Phase 2 Study of Erda-iDRS as Ablative Treatment in Recurrent IR NMIBC

Key eligibility criteria

- Adults (aged ≥18 years)
- Histologically confirmed **recurrent IR NMIBC**, defined as Ta LG/grade 1 *or* Ta LG/grade 2
  - Must have visible disease (≥5 mm) in the bladder and must have not undergone complete/debulking resection or other ablative procedure of bladder tumors following current diagnosis
- Must submit tissue and urine for *FGFR* testing
- Must have **≥1 IBCG risk factor**
  - Multiple Ta LG tumors
  - Solitary LG tumor ≥3 cm
  - Early recurrence (<1 year)
  - Frequent recurrences (>1 per year)
  - Recurrence after prior adjuvant intravesical treatment

→

Erda-iDRS
(N = 140)
Q12W for ~1 year[a]

Primary end point

- Overall CR rate[b]

Secondary end points

- Duration of CR (key)
- CR at 3 months (key)
- TURBT-free survival
- Safety and tolerability
- Patient-reported outcomes

NCT05316155

- MoonRISe-2 is a phase 2 expansion of the first-in-human study in recurrent IR NMIBC
- Response to treatment will be assessed based on cystoscopic visualization (Q12W) and biopsy (if needed)
- The study began in April 2025. Enrollment is complete, with 140 patients enrolled at 52 sites across 7 countries

LG, low-grade; Q12W, every 12 weeks.
[a]4 cycles in absence of disease worsening, recurrence, or unacceptable toxicity and if in CR after cycle 2.
[b]Overall CR rate is defined as negative cystoscopy or positive cystoscopy with a biopsy that is negative for malignancy. If urine cytology is performed, findings that are negative for malignancy or atypical urothelial cells are considered compatible with CR. Patients with non-CR/non-progressive disease at the end of cycle 1 may continue with an additional cycle of erda-iDRS treatment; if patients do not achieve a CR at the end of cycle 2 (around week 24), they should discontinue treatment.

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Patient Baseline Characteristics

Characteristics	Erda-iDRS (N=140)
Age, years, median (range)	73.0 years (43-93)
Sex, male, n (%)	104 (74.3%)
Race, White, n (%)[a]	109 (77.9%)
Recurrent disease, n (%)	140 (100%)
ECOG PS 0, n (%)	118 (84.3%)
Any individual tumors >3 cm, n (%)[b]	12 (8.6%)
No. of lesions, n (%)[c]	
1-3	90 (65.2%)
≥4	48 (34.8%)

Characteristics	Erda-iDRS (N=140)
Sum of lesion(s) longest axes, n (%)[c]	
5 to <10 mm	38 (27.5%)
≥10 to <30 mm	71 (51.4%)
≥30 to <50 mm	16 (11.6%)
≥50 mm	13 (9.4%)
Sum of lesion sizes, median (range), mm[c]	14.5 mm (5-190 mm)
Prior intravesical therapy, n (%)[d]	58 (41.4%)
BCG	26 (18.6%)
Mitomycin C	20 (14.3%)
Gemcitabine	14 (10.0%)
Epirubicin	5 (3.6%)
No. of prior cancer-related surgeries, median (range)	2 (1-13)
TURBT[e]	2 (1-11)
Bladder biopsy[f]	1 (1-6)
Fulguration[g]	1 (1-6)

Clinical cutoff: April 7, 2026.
ECOG PS, Eastern Cooperative Oncology Group performance status.
[a]Other races included Asian (17.1%), Black or African American (4.3%), and Native Hawaiian or Other Pacific Islander (0.7%). [b]n=139. [c]n=138. [d]Other intravesical therapies included pirarubicin (2.1%), cabergoline (1.4%), cretostimogene grenadenorepvec (0.7%), and doxorubicin (0.7%). [e]n=134. [f]n=32. [g]n=15.

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Conclusions

- MoonRISe-2 has fully enrolled a recurrent IR NMIBC population
- Patients had substantial disease burden, with ~35% presenting with ≥4 tumors at baseline
  - The number of prior TURBT procedures ranged from 1 to 11, and 41% had received prior intravesical BCG or chemotherapy
- Phase 3 studies are ongoing with erda-iDRS as adjuvant treatment in *FGFR*-altered IR NMIBC (MoonRISe-1) and BCG-treated papillary-only HR NMIBC (MoonRISe-3)

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https://www.congresshub.com/Oncology/AUA2026/Erda-iDRS/Pieczonka

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- This study was sponsored by Johnson & Johnson
- Erdafitinib was discovered in collaboration with Astex Pharmaceuticals
- Writing support was provided by Nicolisha Narainpersad, PhD, of Parexel, and funded by Johnson & Johnson