MoonRISe-3: A Phase 3 Study of Erda-iDRS, an Erdafitinib Intravesical Drug-Releasing System vs Intravesical Chemotherapy in Patients With Bacillus Calmette–Guérin-Treated High-Risk Non–Muscle-Invasive Bladder Cancer With Susceptible *FGFR* Alterations

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Disclosures

- Johnson & Johnson-– Clinical Trial Funding and Advisory Board Participation
- Full COI disclosure available on the AUA website
- This study is sponsored by Johnson & Johnson

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High Unmet Need in *FGFR*-Altered Papillary-Only HR NMIBC

- TURBT followed by induction and maintenance intravesical BCG is the standard of care for high-risk papillary NMIBC[1-3]
  - The 5-year risk of recurrence with BCG is as high as ~70%, and risk of progression can be up to ~40%[4]
  - Up to 20% of patients are BCG-intolerant, and the ongoing BCG shortage has impacted the rates of eligible patients who receive a full course of BCG induction[5,6]
- After exhausting BCG and other alternatives, treatment guidelines recommend RC; however, RC carries significant morbidity (~60%) and mortality (2-8% within 90 days) and has a negative impact on QoL.
  Fewer than 20% of patients undergo RC in the real world[1,3,7-9]
- *FGFR* alterations are found in ~40% of papillary-only HR NMIBC tumors and may function as oncogenic drivers[10]
- Currently, there are ***no approved treatment options*** for *FGFR*-altered BCG-treated papillary-only HR NMIBC (high-grade Ta or T1)

BCG, bacillus Calmette–Guérin; HR, high-risk; FGFR, fibroblast growth factor receptor; NMIBC, non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor.

1. Holzbeierlein JM, et al. *J Urol.* 2024;211:533-538. 2. Babjuk M, et al. *Eur Urol.* 2022;81:75-94. 3. Witjes JA, et al. Available at: https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Non-muscle-Invasive-Bladder-Cancer-2024.pdf. Accessed April 23, 2026. 4. Sylvester RJ, et al. *Eur Urol.* 2006;49:466-477. 5. Oh C, et al. *ANZJ Surg.* 2025;95:2460-2467. 6. Chun B, et al. *Urology.* 2023;177:74-80. 7. Maibom SL, et al. *BMJ Open.* 2021;11:e043266. 8. Catto JWF, et al. *JAMA.* 2022;327:2092-2103. 9. Musat MG, et al. *Clinicoecon Outcomes Res.* 2022;14:35-48. 10. Catto JWF, et al. *Ann Oncol.* 2024;35:98-106.

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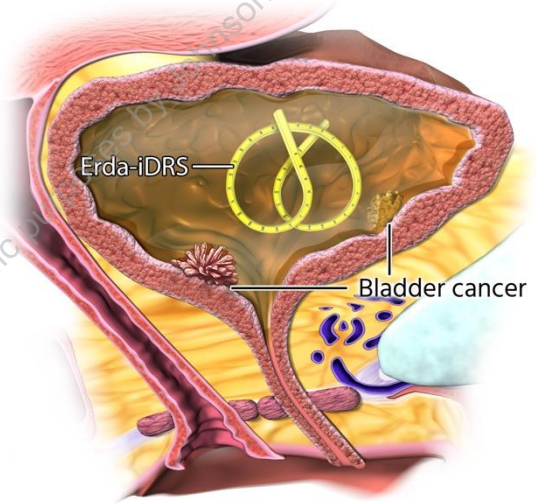
Erda-iDRS for Localized Treatment of *FGFR*-Altered NMIBC

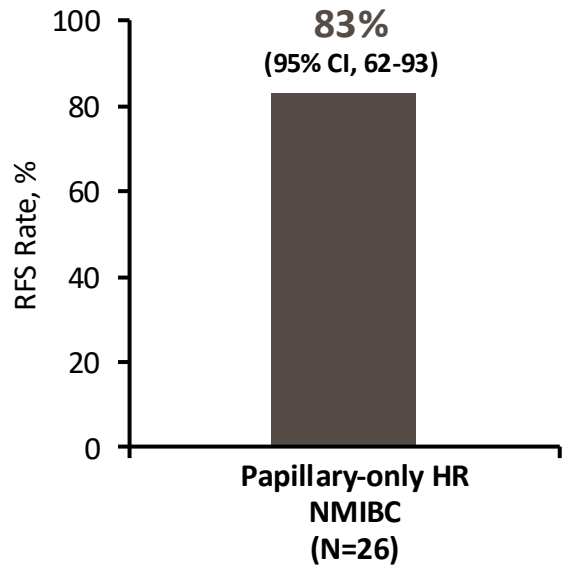
- Oral erdafitinib, a selective pan-FGFR tyrosine kinase inhibitor, is approved for treatment of mUC with susceptible *FGFR3* genetic alterations following progression on prior systemic therapy[1]
- THOR-2 Cohort 1 evaluated *FGFR*-altered papillary-only HR NMIBC; oral erdafitinib prolonged RFS compared with intravesical chemotherapy
  - Median RFS: not reached vs 11.6 months (median follow-up, 18.5 vs 16.6 months), respectively[2]
  - Systemic toxicities included hyperphosphatemia, skin and nail toxicities, and central serous retinopathy[2]

- **Erda-iDRS (TAR-210) is a novel intravesical drug-releasing system designed for sustained local delivery of erdafitinib within the bladder for 3 months**
- Erda-iDRS is inserted using a urinary placement catheter in a brief in-office procedure



- In the **first-in-human study**, erda-iDRS was well tolerated and demonstrated clinical activity in FGFR-altered papillary-only HR NMIBC3

RFS Rate at 12 Months[a,b]



mUC, metastatic urothelial carcinoma; RFS, recurrence-free survival.
[a]RFS was estimated using the Kaplan-Meier method. [b]All 26 treated patients were efficacy-evaluable.
1. BALVERSA® (erdafitinib) [prescribing information]. Horsham, PA: Janssen Products, LP; 2024. 2. Daneshmand S, et al. *Eur Urol.* 2026;89:165-173. 3. Vilaseca A, et al. EUA 2026; March 13-16, 2026; London, UK.

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MoonRISe-3: Phase 3 Study of Erda-iDRS vs Intravesical Chemotherapy in Patients With BCG-Treated, *FGFR*-Altered Papillary-Only HR NMIBC

Key eligibility criteria

- Adults (aged ≥18 years)
- Histologically confirmed **papillary-only HR NMIBC** (no CIS):
  - High-grade Ta or any T1 with complete resection prior to randomization
- **BCG-unresponsive[a]:** High-grade T1 disease at first assessment or high-grade Ta/any T1 disease within 6 months of last BCG or
  BCG-experienced[b]: High-grade Ta/any T1 disease within 6 to 12 months of last BCG, excluding BCG-unresponsive or
  BCG-intolerant: Unable to receive ≥5 BCG doses due to grade ≥2 toxicity requiring permanent BCG discontinuation
- ECOG performance status ≤2
- Refused or ineligible for RC
- Susceptible *FGFR* mutation or fusion by urine or tumor tissue testing[c]

Stratification factors

- T stage (high-grade Ta or any T1)
- Prior BCG treatment (BCG unresponsive[a], experienced[b], or intolerant[d])
- Choice of intravesical chemotherapy (MMC or gemcitabine)

1:1 (N≈220)

R

Erda-iDRS
(n≈110)
Q12W for 2 years

Investigator's choice of single-agent intravesical chemotherapy[1,2]
(n≈110)
MMC or gemcitabine
QW for 6 doses (induction) followed by Q4W for 1-2 years (maintenance)

Primary end point

- Disease-free survival[e]

Secondary end points

- Recurrence-free survival
- Time to next intervention
- Time to disease worsening
- Time to progression
- Overall survival
- Safety and tolerability
- Patient-reported outcomes

NCT06919965

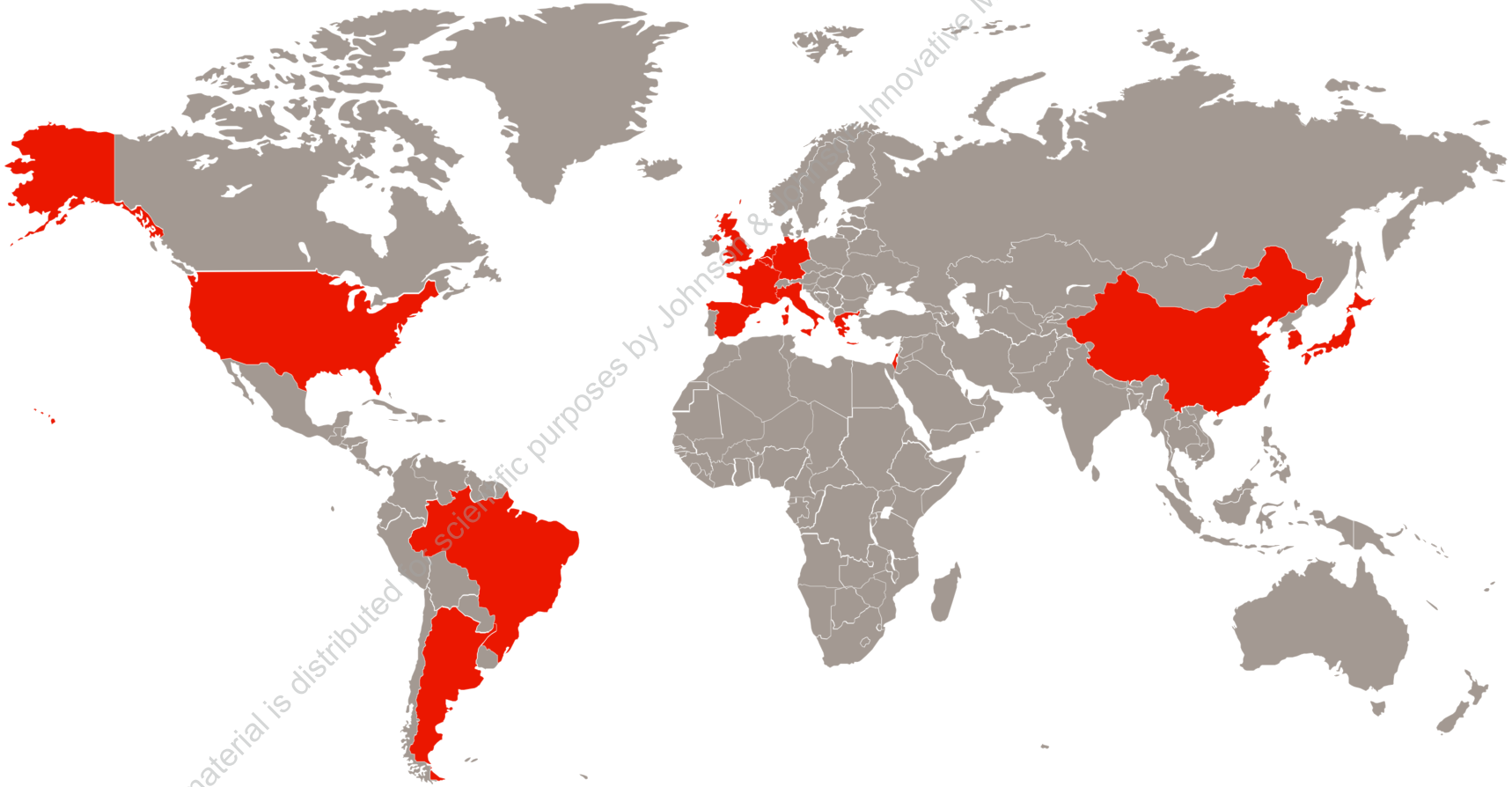
- Recurrence or progression assessed by 12-weekly cystoscopy ± TURBT/biopsy, central pathology, urine cytology and imaging

CIS, carcinoma in situ; ECOG, Eastern Cooperative Oncology Group; MMC, mitomycin C; Q12W, every 12 weeks; Q4W, every 4 weeks; QW, every week; R, randomized; RC, radical cystectomy.
[a]5 of 6 induction doses and either 2 of 3 maintenance or 2 of 6 second induction doses. [b]5 of 6 induction doses ± maintenance. [c]Historical positive allowed if tissue from study is insufficient to inform diagnosis. [d]Unable to receive at least 5 induction doses due to grade ≥2 toxicity requiring permanent BCG discontinuation. [e]Disease-free survival defined as time from randomization to first documented recurrence of HR NMIBC (high-grade Ta, any T1, or CIS), disease progression, or death, whichever occurs first.

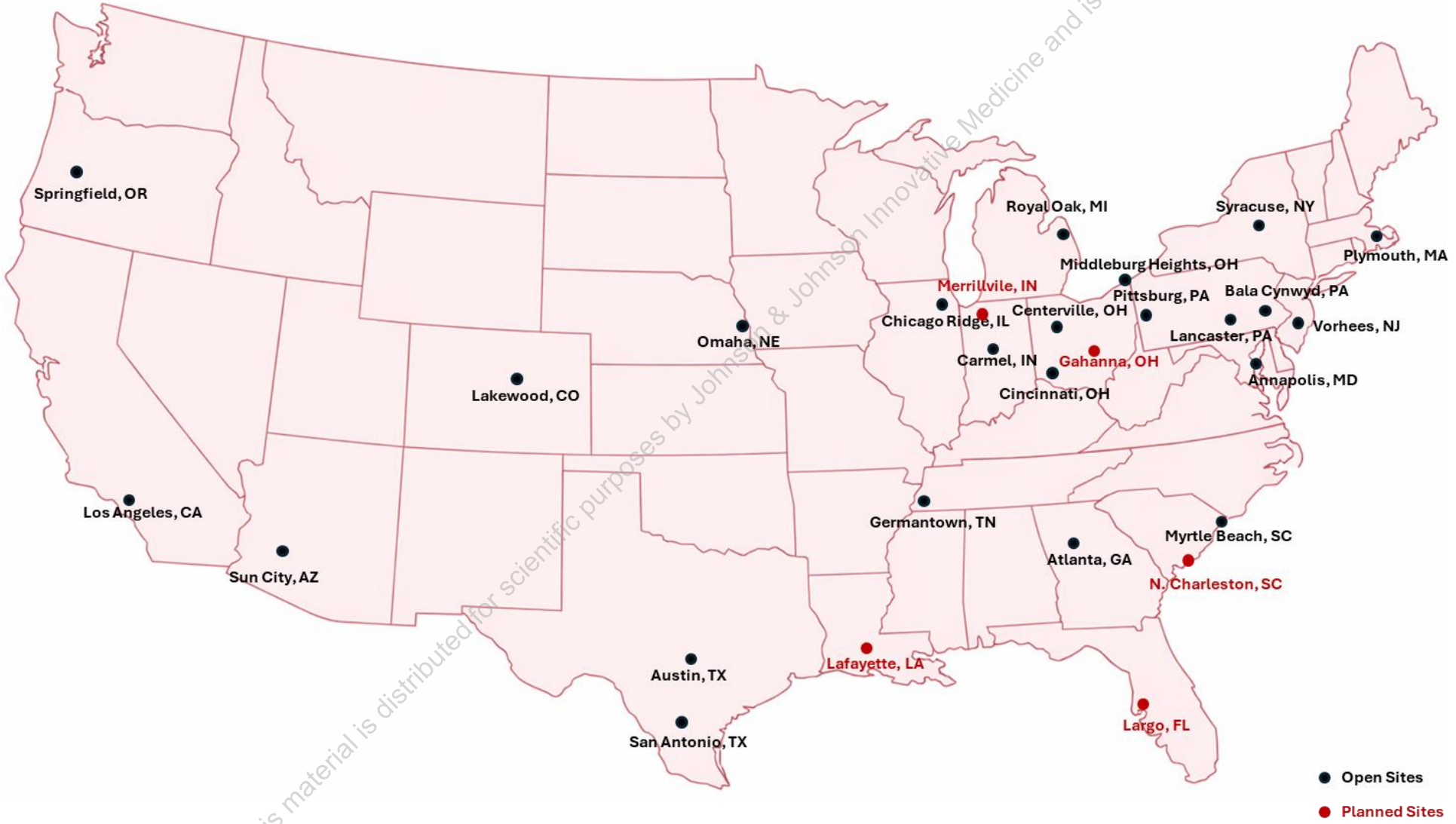
1. Holzbeierlein J, et al. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. Accessed April 23, 2026. 2. Gontero P, et al. Available at: https://bladdercare.com/fileadmin/user_upload/07_Downloads/EAU-Guidelines-on-Non-muscle-Invasive-Bladder-Cancer-2023_2023-03-10-101110_jued.pdf. Accessed April 23, 2026.

Global Footprint for MoonRISe-3

The first patient was enrolled in November 2025. As of March 25, 2026, 340 patients have been screened, and recruitment is ongoing at ~104 sites across 15 countries worldwide.



US Study Sites for MoonRISe-3



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

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