MoonRISe-1: Phase 3 Study of TAR-210, an Intravesical Erdafitinib Releasing System, Versus Intravesical Chemotherapy in Patients With *FGFR*-altered Intermediate-risk Non–muscle-invasive Bladder Cancer

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Presented by R Li at the 120th AUA Annual Meeting; April 26-29, 2025; Las Vegas, NV, USA

Disclosures

- Dr Li has served as a scientific advisor/consultant for Bristol Myers Squibb, Merck, Ferring, Fergene, ArquerDiagnostics, Urogen Pharma, CG Oncology, and Lucence; has served on the clinical trial protocol committee for CG Oncology; and has received research support from Predicine, Veracyte, CG Oncology, and Valar Labs

- This study is sponsored by Janssen Research & Development LLC, a Johnson & Johnson company

Unmet Need in the Treatment of IR NMIBC and Potential for FGFR Inhibition

- Despite available treatment options for patients with IR NMIBC, recurrence rates remain high, underscoring the need for novel effective therapies[1]
- *FGFR* alterations are prevalent in ~75% of IR NMIBC and may function as oncogenic drivers[2-5]
- **Erdafitinib** is a selective pan-FGFR tyrosine kinase inhibitor[6]
  - Oral erdafitinib is approved in the United States to treat adults with locally advanced or mUC with susceptible *FGFR3* alterations following progression on or after at least 1 prior systemic treatment, with additional approvals worldwide[7-11]
- Oral erdafitinib has demonstrated antitumor activity in IR and HR NMIBC populations, limited by challenging systemic toxicities[12-14]

FGFR, fibroblast growth factor receptor; HR, high risk; IR, intermediate risk; mUC, metastatic urothelial carcinoma; NMIBC, non–muscle-invasive bladder cancer.

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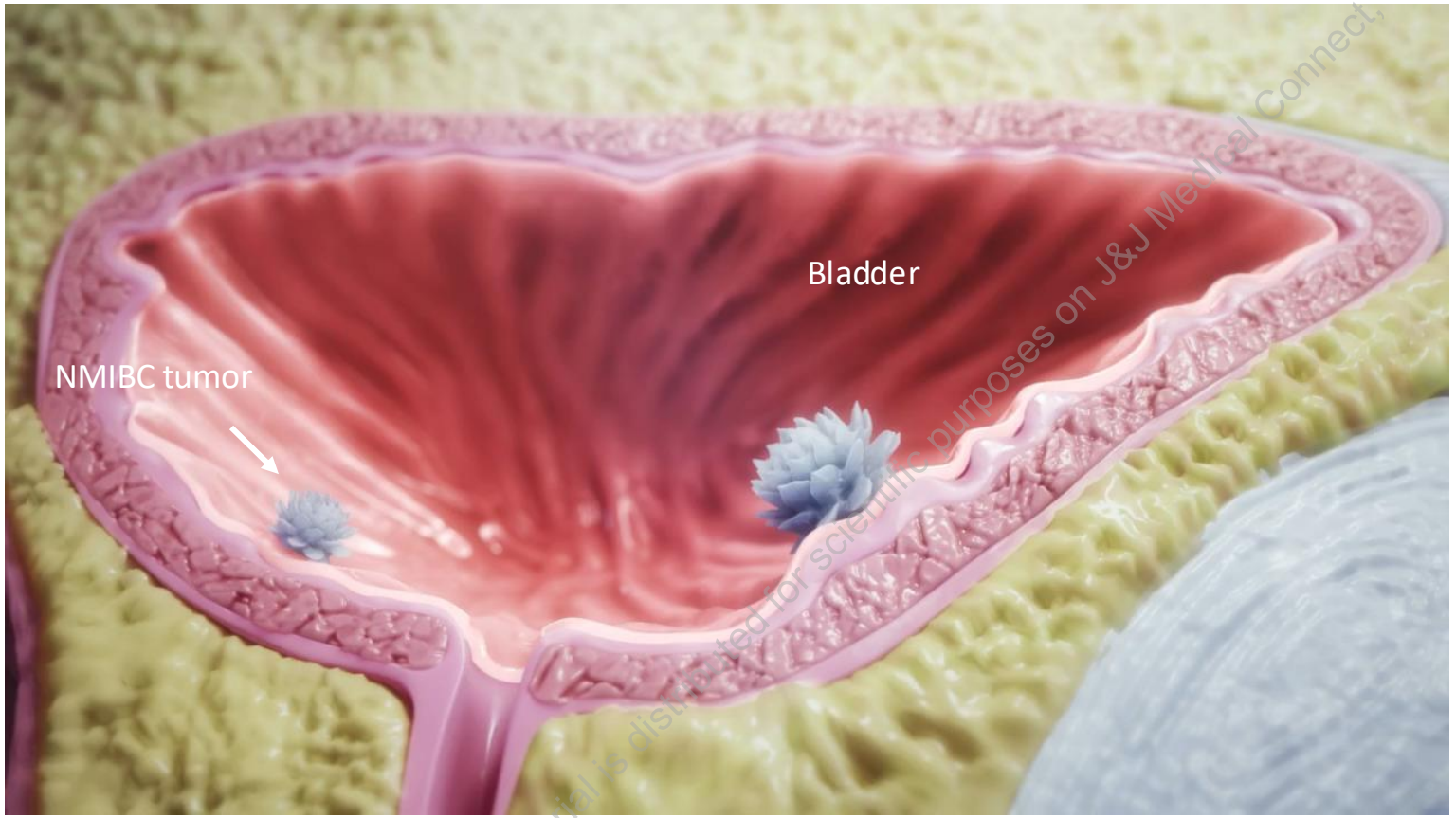
TAR-210 Is a Novel Intravesical Drug-Releasing System Designed for Local Delivery of Erdafitinib for Patients With Bladder Cancer

TAR-210 is a novel intravesical erdafitinib-releasing system designed for sustained local delivery of therapy over 3 months in the bladder



In a first-in-human study, **TAR-210** was well tolerated, with encouraging clinical activity in ***FGFR*-altered IR NMIBC**[1,2]

- CR rate at week 12[a]: 90%
- 9-month DOR rate[b]: 89% (95% CI, 43-98)

TAR-210 is inserted using a urinary placement catheter in a brief in-office procedure

[a]43 patients were treated; 31 patients were efficacy evaluable for CR. [b]DOR rate was estimated using the Kaplan-Meier method.
DOR, duration of response.

1. Vilaseca A, et al. *Ann Oncol* 2023;34:S1343. 2. Vilaseca A, et al. *J Urol*. 2024;211(5S):e987-8. 3. Vilaseca A, et al. TAR-210 Erdafitinib Intravesical Delivery System in Non–Muscle-Invasive Bladder Cancer With Select *FGFR* Alterations: Updated First-in-Human Results. Paper presented at: 119th AUA Annual Meeting; May 3-6, 2024; San Antonio, TX, USA.

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MoonRISe-1: An Open-Label, Multicenter, Randomized Phase 3 Study to Evaluate Efficacy and Safety of TAR-210 vs Intravesical Chemotherapy in Patients With *FGFR*-Altered, Low-Grade IR NMIBC

Key eligibility criteria

- Adults (aged ≥18 years)
- Histologically confirmed **IR NMIBC** (diagnosed ≤90 days prior to randomization):
  - Ta LG/grade 1
    - Primary
    - Recurrent

  —*or*—

  - Ta LG/grade 2
    - Primary
    - Recurrent
- With **≥1 risk factor**[a]
- Susceptible *FGFR2/3* alterations by central or local tissue or urine testing

Stratification factors

- Anticipated choice of intravesical chemotherapy
- Newly diagnosed vs recurrent disease
- Cystoscopic assessment method (white light vs enhanced assessment method)

1:1
(N≈540)

R

TAR-210
(n≈270)
Q12W for 1 year

Investigator's choice of intravesical chemotherapy
(n≈270)
MMC or gemcitabine
QW for 4 to 6 doses (induction)
and maintenance for 6 months to 1 year

Primary end point

- Disease-free survival[b]

Secondary end points

- Time to next-line treatment
- High-grade recurrence-free survival
- Progression-free survival
- Rate of diagnostic and therapeutic urological interventions
- Safety and tolerability

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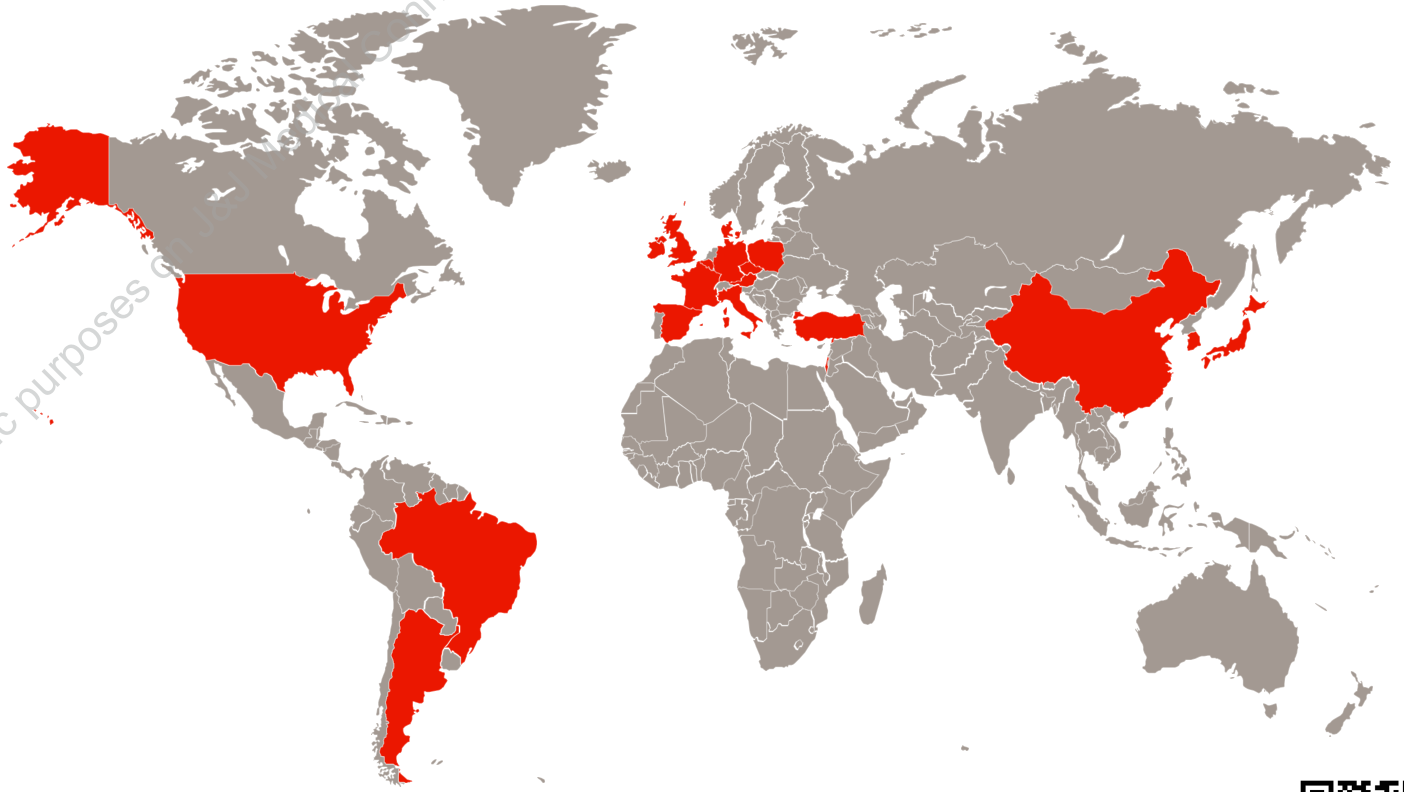
- All visible papillary disease must be fully resected prior to randomization
- Assessments of recurrence or progression include urine cytology, cystoscopy, for-cause TURBT or biopsy of bladder lesions, ultrasound, and urography
- The follow-up phase for patients meeting the primary end point is up to ≈5 years

[a]Risk factors include multiple Ta LG tumors, tumors ≥3 cm, early (<1 year) recurrence, frequent (>1 per year) recurrences, or recurrence after prior adjuvant intravesical chemotherapy. [b]Disease-free survival defined as time from randomization to first documented recurrence of any-grade NMIBC, disease progression, or death from any cause, whichever occurs first.
LG, low grade; MMC, mitomycin C; NMIBC, non–muscle-invasive bladder cancer; Q12W, every 12 weeks; QW, every week; R, randomized; TURBT, transurethral resection of bladder tumor.

Global Enrollment for MoonRISe-1

- The MoonRISe-1 study opened for enrollment on April 10, 2024
  - The first patient was randomized on July 8, 2024
- Recruitment is planned at 198 sites and is ongoing

Enrollment is planned at 198 sites in 19 countries across 4 continents



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Acknowledgements

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Additional AUA 2025 Learning Lab presentations on TAR-210 and TAR-200:

- **MoonRISe-1 Clinical Trials in Progress, Bladder Cancer**
  April 28, 2025; 9:08 AM - 9:16 AM; Learning Lab
- **SunRISe-5 Clinical Trials in Progress, Bladder Cancer**
  April 28, 2025; 9:40 AM - 9:48 AM; Learning Lab
- **MoonRISe-3 Clinical Trials In Progress, Bladder Cancer**
  April 28, 2025; 9:56 AM - 10:04 AM; Learning Lab

- This study is sponsored by Janssen Research & Development LLC, a Johnson & Johnson company
- Erdafitinib was discovered in collaboration with Astex Pharmaceuticals
- Writing support was provided by Benjamin Ricca of Johnson & Johnson

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