MoonRISe-1: Phase 3 Study of TAR-210, an Erdafitinib Intravesical Delivery System, Versus Intravesical Chemotherapy in Patients With Intermediate-Risk Non–Muscle-Invasive Bladder Cancer With Susceptible *FGFR* Alterations

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Disclosures

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

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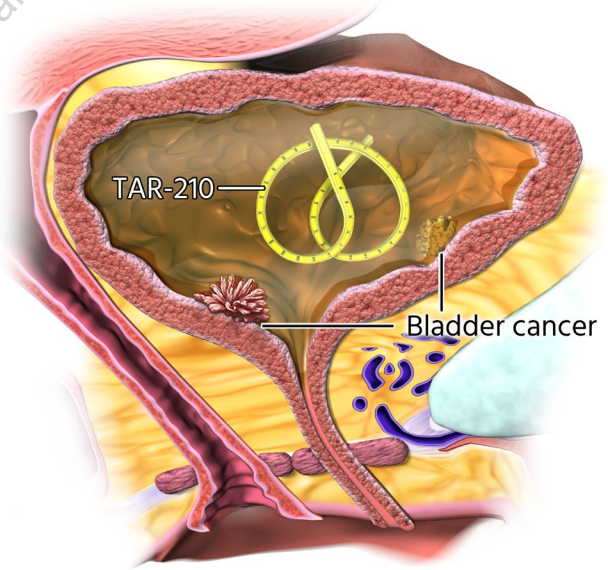
TAR-210 is a Novel Intravesical Targeted Releasing System Designed to Deliver Erdafitinib for Patients With Bladder Cancer

- Despite available treatment options for patients with IR NMIBC, recurrence rates remain high, underscoring the need for effective therapies[1]
- *FGFR* alterations are prevalent in ~50% to 80% of low-grade NMIBC and may function as oncogenic drivers[2-4]
- **Erdafitinib** is a selective pan-FGFR tyrosine kinase inhibitor[5]
  - Oral erdafitinib (Balversa®) 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 across geographies[6-9]
- Oral erdafitinib demonstrated clinical efficacy in HR and IR NMIBC populations, but was limited by challenging systemic toxicities[10-12]
  - In an interim analysis of THOR-2 Cohort 3, 15/18 patients with *FGFR*-altered IR NMIBC had CR (83%) with median DOR of 12.8 months[13]

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



TAR-210 is inserted into the bladder through a dedicated urinary placement catheter and removed via cystoscopy.

In a first-in-human study, TAR-210 was well tolerated with promising clinical activity in *FGFR*-altered **HR NMIBC (RFS rate: 82%)** and **IR NMIBC (CR rate: 87%)**.[14] Updated data will be presented later today.[15]

CR, complete response; FGFR, fibroblast growth factor receptor; HR, high risk; IR, intermediate risk; mUC, metastatic urothelial carcinoma; NMIBC, non–muscle-invasive bladder cancer; RFS, recurrence free survival.

1. Ritch CR, et al. *J Urol.* 2020;203:505-511. 2. Hernández S, et al. *J Clin Oncol.* 2008;24:3664-3671. 3. Knowles MA, Hurst CD. *Nat Rev Cancer.* 2014;15:25-41. 4. Khalid S, et al. *Eur Urol Open Sci.* 2020;21:61-68. 5. Perera TPS, et al. *Mol Cancer Ther.* 2017;16:1010-1020. 6. BALVERSA® (erdafitinib) [package insert]. Horsham, PA: Janssen Products, LP; 2024. 7. Loriot Y, et al. *N Engl J Med.* 2019;381:338-348. 8. Siefker-Radtke AO, et al. *Lancet Oncol.* 2022;23:248-258. 9. Loriot Y, et al. *N Engl J Med.* 2023;21:1961-1971. 10. Daneshmand S, et al. *J Clin Oncol.* 2023;41(Suppl 6):504. 11. Catto JWF, et al. *J Clin Oncol.* 2023;41(Suppl 6):503. 12. Catto JWF, et al. *Ann Oncol.* 2024;35:98-106. 13. Daneshmand S, et al. *Urol Oncol: Sem Orig Investig.* 2024;42:S58. 14. Vilaseca A, et al. *Ann Oncol.* 2023;34:S1343. 15. Vilaseca A, et al. AUA, 2024.

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

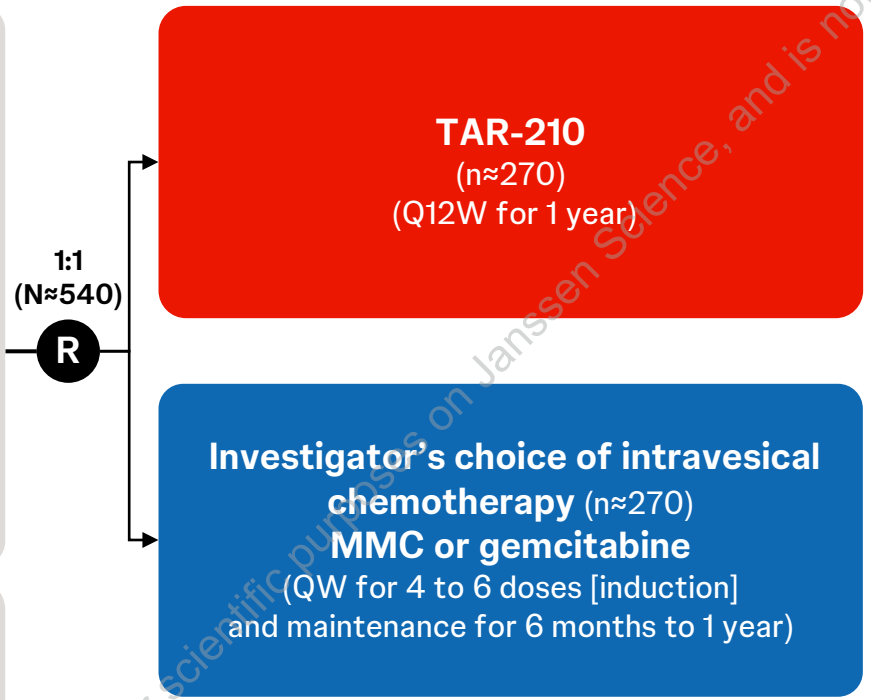
Key eligibility criteria

- Adults (aged ≥18 years)
- Histologically confirmed **IR NMIBC**:
  - Ta LG/grade 1
    - Recurrent or
    - Primary: Multifocal, or ≥3 cm

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

Stratification factors

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



Primary end point

Disease-free survival[b]

Key secondary end points

- Time to next treatment
- High grade recurrence-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 endpoint is up to ≈5 years

LG, low grade; MMC, mitomycin C; QW, every week; Q12W, every 12 weeks; R, randomized; TURBT, transurethral resection of bladder tumor.
[a]Risk factors include multiple Ta LG tumors, tumors >3 cm, early (≤1 year) recurrence, frequent (>1 per year) recurrences, or recurrence after 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.

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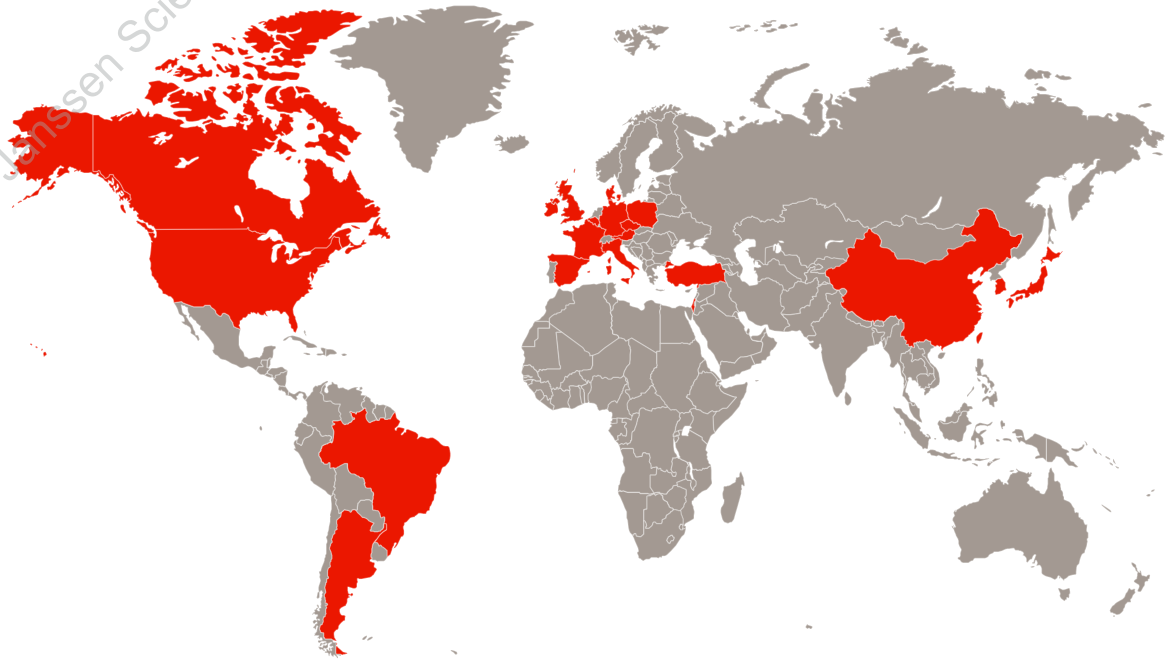
Global Enrollment for MoonRISe-1

- The MoonRISe-1 study opened for enrollment on April 10, 2024
- Recruitment is planned at 200 sites
  - As of April 29, enrollment is open at 7 sites in the United States and 1 in Israel, with 5 patients in molecular screening

Enrollment is planned at 200 sites in 20 countries across 4 continents



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Acknowledgments

https://www.congresshub.com/Oncology/AUA2024/TAR-210/Li

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

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Vilaseca A, et al. First-in-human Study of TAR-210 Erdafitinib Intravesical Delivery System In Patients With Non–Muscle-Invasive Bladder Cancer With Select *FGFR* Alterations

AUA #PD48-02

Sunday, 1:10 pm (304A)

Poster and Podium Sessions – PD48: Bladder Cancer: Non-invasive III