Phase 3 Study of TAR-210 (Intravesical Erdafitinib Releasing System) vs Intravesical Chemotherapy in Patients With BCG–treated High-risk Non–muscle-invasive Bladder Cancer

Neal D Shore[1], Wolfgang Jessner[2], Maarten Schuit[3], Spyros Triantos[2], Nicole L Stone[2], Sydney Akapame[2], Hussein Sweiti[2], Félix Guerrero-Ramos[4]

[1]Carolina Urologic Research Center, Myrtle Beach, SC; [2]Johnson & Johnson, Spring House, PA; [3]Johnson & Johnson, Breda, the Netherlands; [4]Department of Urology, Hospital Universitario 12 de Octubre, Madrid, Spain.

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

Disclosures

- Dr Shore has received research funding from Amgen, Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, CG Oncology, Dendreon, Exelixis, Ferring, Janssen, Merck, MT Group, Novartis, Pfizer, Steba Biotech, Theralase, Tolmar, Urogen, and Zenflow; and consulting/advisory fees from Amgen, Astellas, AstraZeneca, AuraBiosciences, Bayer, Bristol Myers Squibb, CG Oncology, Clarity Pharmaceuticals, Daiichi Sankyo, Dendreon, Ferring, Janssen, Lantheus, Lilly, MDxHealth, Novartis, Pfizer, Photocure, Sumitomo, Telix Pharmaceuticals, Tolmar, and Urogen

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

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

High Unmet Need in Papillary-only HR NMIBC

- TURBT followed by intravesical BCG is standard of care for high-grade papillary NMIBC[1,2]; however:
  - ~60% of patients have recurrence (BCG-unresponsive or BCG-experienced) or progression within 12 months of BCG therapy[3,4]
  - ~20% of patients are BCG-intolerant[5]
- After exhausting BCG and other alternatives, treatment guidelines recommend RC[1,6]; however:
  - RC carries significant morbidity (~60%), mortality (2-8% within 90 d), and negative impact on QoL[1,7-9]
- *FGFR* alterations are found in 35-40% of papillary-only HR NMIBC tumors and may function as oncogenic drivers[10]

Despite recent approvals of novel agents for HR NMIBC CIS, there remains an unmet need with ***no approved treatment options*** for papillary-only HR NMIBC (high-grade Ta or T1), recurrent after BCG or BCG-intolerant, and no treatments targeting *FGFR*-altered disease

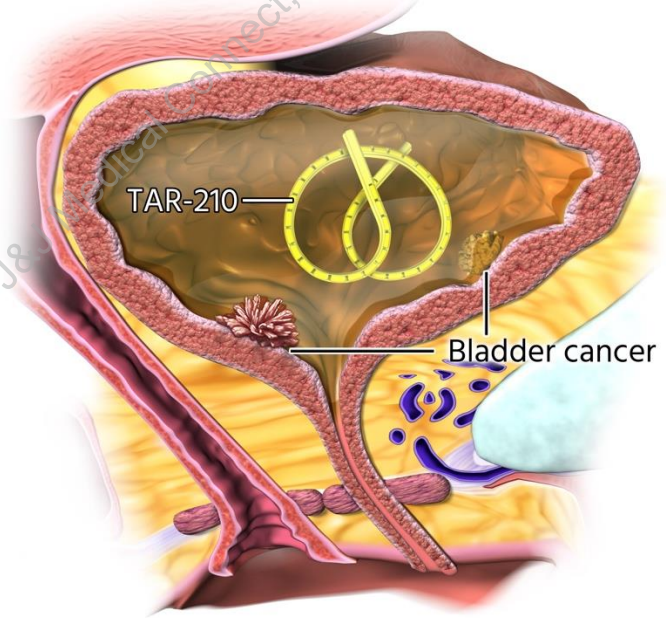
BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; DFS, disease-free survival; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor.
1. EAU. Available at: https://d56bochluxqnz.cloudfront.net/documents/full-guideline/EAU-Guidelines-on-Non-muscle-Invasive-Bladder-Cancer-2023_2023-03-10-101110_jued.pdf. 2. Babjuk M, et al. *Eur Urol* 2022;81:75-94. 3. Sylvester RJ, et al. *Eur Urol*. 2006;49:466-477. 4. Mmeje CO, et al. *Eur Urol*. 2016;70:778-785. 5. Oddens J, et al. *Eur Urol*. 2013;63:462-473 6. Holzbeierlein JM, et al. *J Urol.* 2024;211:533-538. 7. Hautmann RE, et al. *J Urol*. 2010;184:990-4. 8. Maibom SL, et al. *BMJ Open*. 2021;11:e043266. 9. Marqueen KE, et al. *JNCI Cancer Spectr*. 2018;2:pky075. 10. Catto JWF, et al. *Ann Oncol* 2024;35:98-106.

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

TAR-210 Is a Novel Intravesical Drug-Releasing System Designed to Deliver Erdafitinib to the Bladder

- Erdafitinib is a selective pan-FGFR tyrosine kinase inhibitor[1]
  - Oral erdafitinib has US approval for *FGFR3*-altered mUC following progression after prior systemic treatment, with additional approvals worldwide[2-6]
- In THOR-2, **oral erdafitinib** showed preliminary evidence of prolonged RFS vs intravesical chemotherapy in patients with papillary-only HR NMIBC harboring *FGFR* alterations (12-month RFS rate[a,b]: 77% vs 41%)[7]

TAR-210 is a novel intravesical erdafitinib-releasing system designed for sustained exposure over 3 months in the bladder



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

In a first-in-human study, **TAR-210** was well tolerated, with encouraging clinical activity in *FGFR*-altered papillary-only HR NMIBC (12-month RFS rate[b,c]: 90%)[8-10]

[a]49 and 24 patients were randomized to receive oral erdafitinib and intravesical chemotherapy, respectively. [b]RFS was estimated using the Kaplan-Meier method. [c]All 21 treated patients were efficacy evaluable.
FGFR, fibroblast growth factor receptor; HR, high risk; mUC, metastatic urothelial carcinoma; NMIBC, non–muscle-invasive bladder cancer; RFS, recurrence-free survival.

1. Perera TPS, et al. *Mol Cancer Ther* 2017;16:1010-20. 2. BALVERSA® (erdafitinib) [package insert]. Horsham, PA: Janssen Products, LP; 2024. 3. BALVERSA® (erdafitinib) [summary of product characteristics]. Beerse, Belgium: Janssen-Cilag International NV; 2024. 4. Loriot Y, et al. *N Engl J Med* 2019;381:338-48. 5. Siefker-Radtke AO, et al. *Lancet Oncol* 2022;23:248-58. 6. Loriot Y, et al. *N Engl J Med* 2023;21:1961-71. 7. Catto JWF, et al. *Ann Oncol* 2024;35:98-106. 8. Vilaseca A, et al. *Ann Oncol* 2023;34:S1343. 9. Vilaseca A, et al. *J Urol*. 2024;211(5S):e987-8. 10. 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.

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

MoonRISe-3: Phase 3 Study of TAR-210 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**:
  - High-grade Ta
    —*or*—
    Any T1 (no CIS)
  - Recurrent after BCG
    —*or*—
    Intolerant of BCG
- ECOG performance status of ≤2
- Susceptible *FGFR* mutation or fusion by urine or tumor tissue testing

Stratification factors

- T stage (high-grade Ta or any T1)
- Prior BCG treatment (BCG unresponsive, experienced, or intolerant)
- Choice of intravesical chemotherapy

1:1
(N≈220)

R

TAR-210
(n≈110)
Q12W for 2 years

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

Primary end point

- Disease-free survival[a]

Key secondary end points

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

NCT06919965

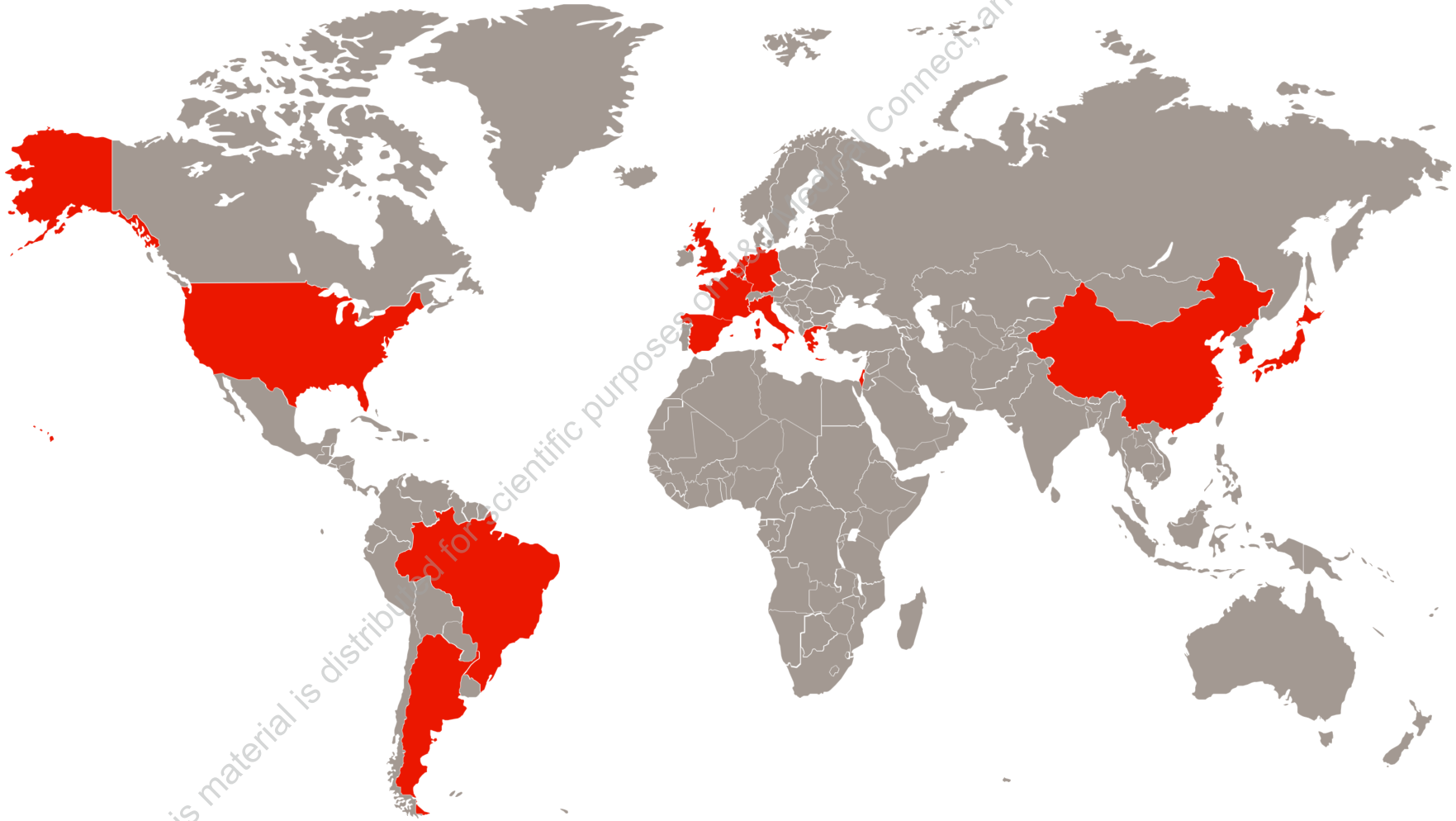
- Assessments of recurrence or progression will be based on central urine cytology, bladder biopsy, and imaging results
- After a positive interim analysis, the IDMC may recommend a crossover option for patients with recurrence in the intravesical chemotherapy arm

[a]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 from any cause, whichever occurs first.
IDMC, independent data monitoring committee; MMC, mitomycin C; NMIBC, non–muscle-invasive bladder cancer; Q12W, every 12 weeks; Q4W, every 4 weeks; QW, every week; R, randomized.

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

Global Footprint for MoonRISe-3

Enrollment is planned at 105 sites in 15 countries across 4 continents



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

https://www.congresshub.com/Oncology/AUA2025/ErdaRIS/Shore

Scan the QR code

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

- 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

Online learning
via JnJInstitute.com

Why wait?

Scan to sign in
or register now

J&J
Institute

Stay ahead with bladder cancer education from the Johnson & Johnson Institute

Access Bladder Cancer Educational Offerings

Enabling learning experiences and centralized access to connect healthcare professionals with bladder cancer educational content, videos, and more