SunRISe-5: A Phase 3, Randomized, Open-Label Study of TAR-200 Compared With Intravesical Chemotherapy After Bacillus Calmette-Guérin in Recurrent High-Risk Non–Muscle-Invasive Bladder Cancer

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Disclosures

- S Porten is an advisory board member for Vesica Health, is a consultant for Photocure, Stryker, and Natera, and has received research funding from Oncuria and Photocure

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

Addressing Unmet Needs in Patients With HR NMIBC Recurrent After BCG Treatment

- Standard of care for papillary disease–only HR NMIBC is TURBT, followed by intravesical BCG treatment[1-3]
  - Between 12% and 78% of patients with HR NMIBC experience disease recurrence after BCG treatment[4-7]
- Additional BCG is **not effective in early recurrences** (within 1 year) and is **not recommended by guidelines**[1,3,8]
- RC is the current standard of care for early BCG-unresponsive recurrence (within 1 year) of papillary disease–only HR NMIBC[1,3]
  - RC is a life-changing operation associated with considerable morbidity, mortality, and impact on QoL[9,10]
  - Many patients either refuse or are ineligible for RC[1,11]
- Approved treatment options for HR NMIBC are limited and are restricted to patients with CIS[12-14]

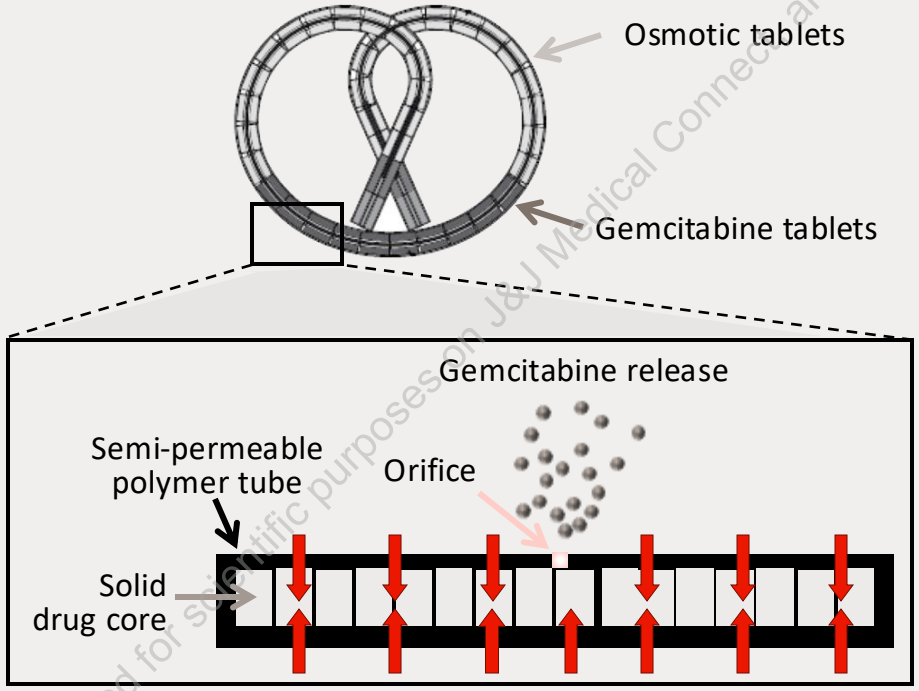
There is a high unmet need to develop ***bladder-sparing, localized treatments*** for ***patients with recurrent papillary disease-only HR NMIBC***

BCG, bacillus Calmette-Guérin; CIS, carcinoma in situ; HR NMIBC, high-risk non–muscle-invasive bladder cancer; QoL, quality of life; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor.

1. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 2. Babjuk M, et al. *Eur Urol* 2022;81:75-94. 3. AUA/SUO Guidelines. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. 4. Grimm M-O, et al. *Eur Urol* 2020;78:690-698. 5. Contieri R, et al. *Eur Urol Oncol*. 2023;6:590-596. 6. Ritch CR, et al. *J Urol*. 2020;203:505-511. 7. Sylvester RJ, et al. *Eur Urol.* 2006;49:466-477. 8. Steinberg RL, et al. *Bladder Cancer*. 2016;2:215-224. 9. Marqueen KE, et al. *JNCI Cancer Spectr*. 2018;2:pky075. 10. Edmondson AJ, et al. *J Cancer Surviv*. 2017;11(4):453-461. 11. Musat MG, et al. *Clinicoecon Outcomes Res.* 2022;14:35-48. 12. Balar AJ, et al. *Lancet Oncol.* 2021;22:919-930. 13. ADSTILADRIN® (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 2024. 14. Chamie K, et al. *NEJM Evid*. 2023;2(1):EVIDoa2200167.

TAR-200 Is an Intravesical Drug Releasing System Designed for Sustained Delivery of Gemcitabine in the Bladder[1-4]

TAR-200 Mini-Tablet Design



Results from SunRISe-1 (NCT04640623) support further investigation of ***TAR-200 monotherapy in patients with BCG-unresponsive HR NMIBC***[5,6]

1. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 2. Tyson MD, et al. *J Urol.* 2023:209:890-900. 3. van Valenberg FJP, et al. *Eur Urol Open Sci.* 2024;62:8-15. 4. Daneshmand , et al. *Urol Oncol.* 2025;S1078-1439(24)01044-5. 5. Jacob J, et al. Presented at AUA 2025. 6. Guerrero-Ramos F, et al. Presented at AUA 2025.

SunRISe-5 Is an Open-Label, Multicenter Phase 3 Study

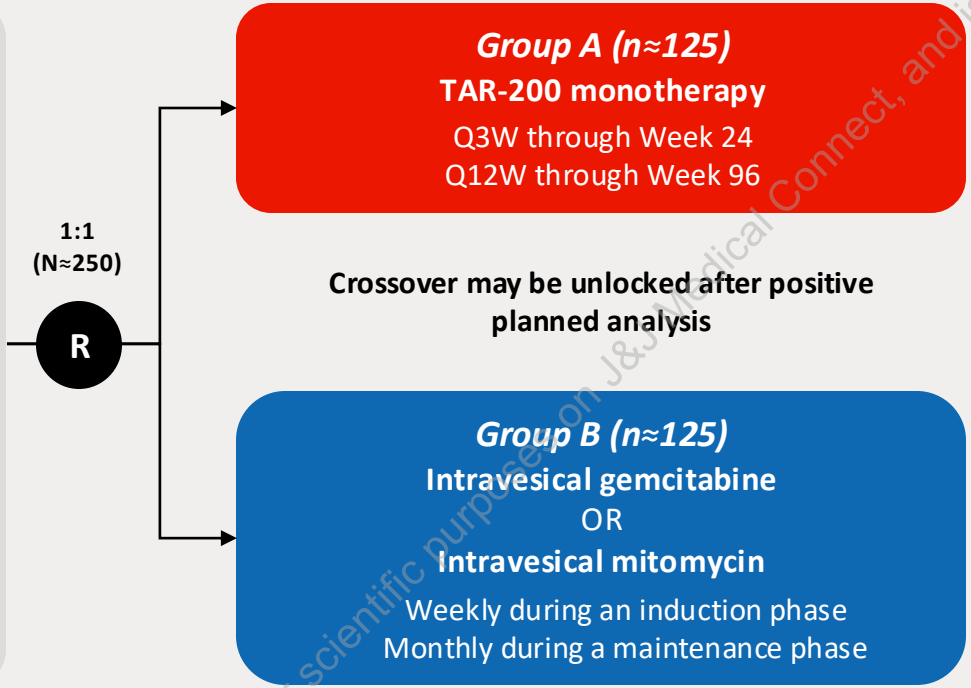
NCT06211764

Key eligibility criteria

- Histologically confirmed, papillary-only HR NMIBC (high grade Ta or any T1),[1] recurrent within the first year of last dose of BCG
- No CIS at time of papillary recurrence
- RC refusing or ineligible
- ECOG PS <3

Stratification factors

- T-stage (high grade Ta or any T1)
- Prior BCG treatment (BCG-unresponsive or BCG-experienced)



Primary end point

- Disease-free survival

Secondary end points

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

- Disease-free survival is defined as time from randomization to first recurrence of HR NMIBC (high-grade Ta, any T1 or CIS), progression, or any-cause death, whichever occurs first

The study will evaluate whether TAR-200 will prolong disease-free survival when compared with intravesical chemotherapy in patients with papillary disease-only HR NMIBC recurrent after BCG therapy who refuse or are unfit for RC

ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; PRO, patient-reported outcome; Q3W, every 3 weeks; Q12W, every 12 weeks; R, randomized.

1. EAU Guidelines. Edn. presented at the EAU Annual Congress Milan 2023. ISBN 978-94-92671-19-6.

Target Patient Population for SunRISe-5

- Patients enrolled in the study include those with recurrence of papillary-only HR NMIBC (HG Ta or any T1, no CIS) within 12 months of last dose of BCG

Definition of minimum prior BCG therapy in the SunRISe-5 target population

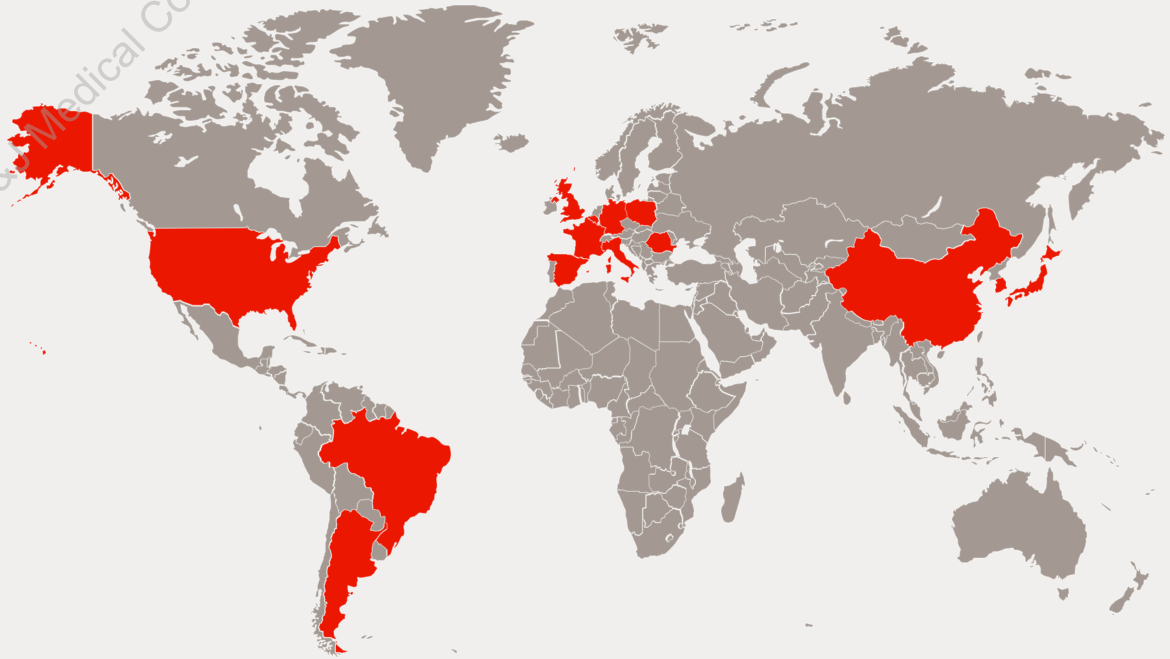
	Minimum BCG Therapy	Timing of Recurrence
BCG-unresponsive[1]	Received adequate Induction (5 of 6 doses) **AND** either 2 of 3 doses of Maintenance **OR** 2 of 6 doses of second Induction	Recurred with high-grade T1 disease at first disease assessment after Induction **OR** high-grade Ta/any T1 disease within 6 months
BCG-experienced *Does not meet BCG-unresponsive definition*	Received adequate Induction (5 of 6 doses) with or without Maintenance therapy	Recurred with high-grade Ta/any T1 disease within 12 months

1. US Food and Drug Administration. Available at: https://www.fda.gov/media/101468/download.

SunRISe-5 Is Ongoing

- First global site opened March 29, 2024
- SunRISe-5 is completing recruitment at 122 sites across Argentina, Belgium, Brazil, China, France, Germany, Italy, Japan, Poland, Romania, South Korea, Spain, the United Kingdom, and the United States

Enrollment occurred at 122 sites across 14 countries



https://www.congresshub.com/Oncology/AUA2025/TAR-200/Porten

Scan the QR code

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Ongoing studies of TAR-200:

- **SunRISe-1**
  BCG-unresponsive HR NMIBC
  (Cohorts 1-3: CIS; Cohort 4: papillary-only)
  NCT04640623
  Cohort 2 and Cohort 4 were presented in the P2 Plenary Session
- **SunRISe-3**
  BCG-naive HR NMIBC
  NCT05714202
- **SunRISe-4**
  Neoadjuvant MIBC
  NCT04919512
- **SunRISe-5**
  Papillary-only, BCG-exposed,
  RC-ineligible/-refusing, recurrent HR NMIBC
  NCT06211764
  Presented here

Additional AUA 2025 presentations on TAR-200:

- **SunRISe-1 Cohort 2 1-Year Durability Results**
  Venetian Ballroom, April 26, 2025; 10:50 AM-11:00 AM; Plenary Session
- **SunRISe-1 Cohort 4 Interim Analysis Results**
  Venetian Ballroom, April 26, 2025; 11:00 AM-11:10 AM; Plenary Session

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