SunRISe-3: TAR-200 Plus Cetrelimab or TAR-200 Versus Intravesical Bacillus Calmette–Guérin (BCG) in Patients With BCG-Naive High-Risk Non-Muscle-Invasive Bladder Cancer

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Disclosures

- Dr Chang is a consultant/advisor for AstraZeneca, GLG, Janssen, KDx diagnostics, Lantheus, Lynx Dx, Merck, Nonagen, Pacific Edge, Pfizer, Prokarium, Tu Therapeutics, Urogen, Vesica Health and Virtuoso Surgical; and has been involved in a scientific studies or received research funding from Ferring, National Institute of Health, and NantBio

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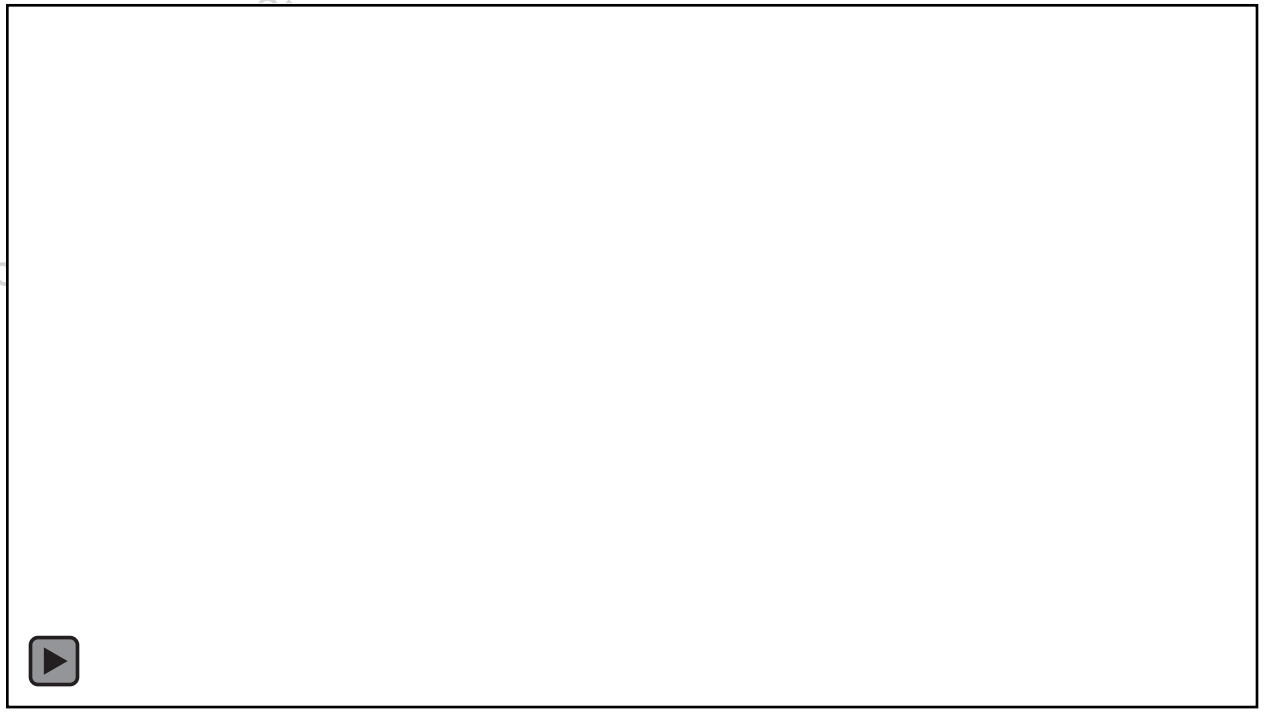
TAR-200 Is Designed to Address the Unmet Need in Patients With BCG-Naive HR NMIBC

- Standard of care for patients with HR NMIBC is transurethral resection of the bladder tumor (biopsy only for CIS) followed by intravesical BCG[1,2]
  - However, BCG is associated with toxicities[2,3] and lacks a durable response in a significant proportion of patients[2,4]
- Interim results from SunRISe-1 (NCT04640623) support investigation of TAR-200 in patients with BCG-naïve HR NMIBC[5]

TAR-200 is a novel targeted releasing system designed for sustained, local delivery of gemcitabine in the bladder[6,7]



TAR-200 is placed using a urinary placement catheter in a **brief in-office procedure**

CIS, carcinoma in situ; HR NMIBC, high risk non–muscle-invasive bladder cancer.

1. Lightfoot AJ, et al. *Scientific World Journal.* 2011;11:602-613. 2. NCCN Clinical Practice Guidelines in Oncology. Bladder cancer. Version 2.2024. 3. Kikuchi E, et al. *Int J Urol.* 2020;27:108-116. 4. TICE® BCG [package insert]. Durham, NC: Organon Teknika Corporation LLC; 2009. 5. Jacob J, et al. AUA 2024; May 3-6, 2024; San Antonio, TX, USA. Abstract #24-7214. 6. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 7. Tyson MD, et al. *J Urol.* 2023;209:890-900.

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SunRISe-3 (NCT05714202) Is a Phase 3, Open-Label, Multicenter Randomized Study

Key eligibility criteria

- Patients with histologically confirmed HR NMIBC (high grade Ta, any T1, or CIS)
- BCG naive (no prior BCG or last exposure >3 years prior to randomization)

Additional criteria:

- Aged ≥18 years
- ECOG PS of 0, 1, or2
- All visible papillary disease must be fully resected (absent) prior to randomization and documented at baseline cystoscopy
- Local urine cytology at screening must be negative or atypical for high-grade urothelial carcinoma in patients with papillary-only disease
- All adverse events associated with any prior surgery and/or intravesical therapy must have resolved to CTCAE v5.0 grade <2 prior to date of randomization

1:1:1 (N≈1050)

R

Group A (n≈350)
TAR-200 + cetrelimab[a]

Group C (n≈350)
TAR-200

Group B (n≈350)
BCG

Primary end point

Event-free survival

Time from randomization to first occurrence of:

- High-risk disease recurrence
- Disease progression[b]
- Any-cause death

For patients with CIS, persistent disease at 6 months is also an EFS event

Secondary end points

- Overall CR rate (CIS only)[c]/duration of CR[d]
- Recurrence-free survival
- Time to progression
- Overall survival
- Cancer-specific survival
- Safety and tolerability
- Patient-reported outcomes

CR, complete response, CTCAE, Common Terminology Criteria for Adverse Events; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival.
[a]Cetrelimab is an anti–programmed death-1 antibody. [b]Progression is defined as stage increase from Ta to T1 or from CIS to T1 or progression to MIBC (T≥2) or to lymph node (N+) or distant (M+) disease (whichever occurs first).
[c]Proportion of patients with CIS who have no presence of high-risk disease at 6 months. [d]Time from first CR achieved to first evidence of recurrence, progression, or any-cause death, whichever occurs first.

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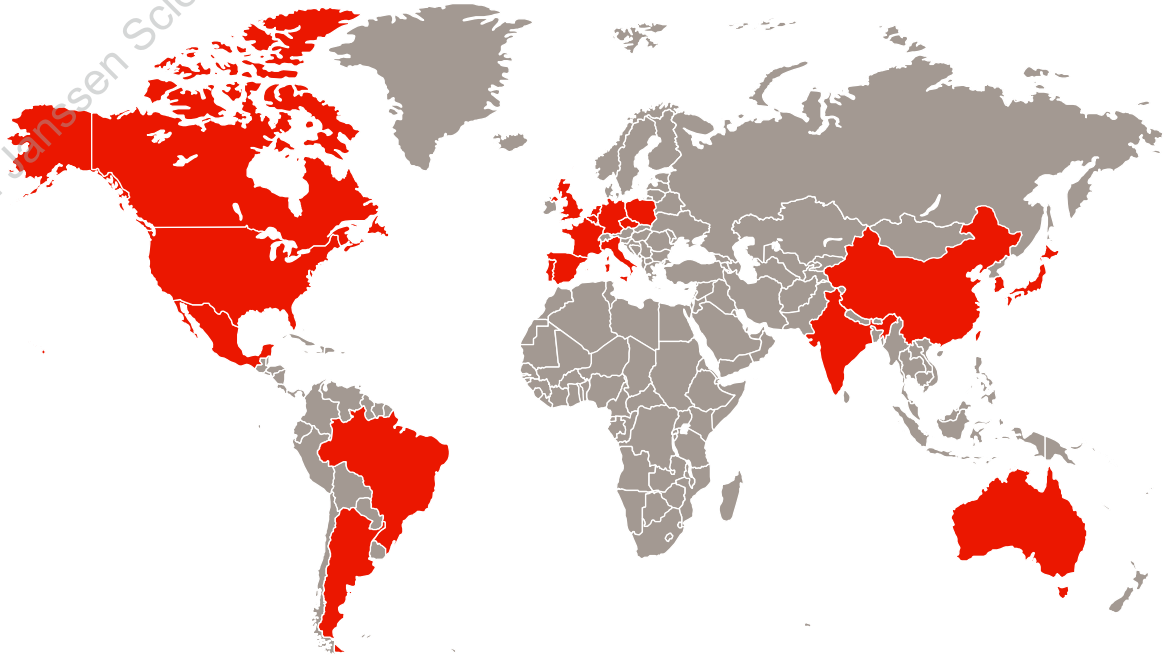
SunRISe-3 Is Currently Ongoing and Enrolling Patients

- The SunRISe-3 study opened for enrollment in March 2023, with 1406 patients screened and 915 patients randomized as of April 23, 2024
- SunRISe-3 has recruited in Argentina, Australia, Belgium, Brazil, Canada, China (including Taiwan), Czechia, France, Germany, India, Italy, Japan, Mexico, Netherlands, Poland, Portugal, South Korea, Spain, the United Kingdom, and the United States

SunRISe-3 study recruits at 231 sites across 20 countries



Acknowledgments

https://www.congresshub.com/Oncology/AUA2024/TAR-200/Chang

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

Ongoing studies of TAR-200:

- **SunRISe-1**
  BCG-unresponsive HR NMIBC
  (cohorts 1-3: CIS; cohort 4: papillary only)
  NCT04640623
- **SunRISe-2**
  RC-ineligible/-refusing MIBC
  NCT04658862
- **SunRISe-3**
  BCG-naive HR NMIBC
  NCT05714202
  Presented here
- **SunRISe-4**
  Neoadjuvant MIBC
  NCT04919512
- **SunRISe-5**
  Papillary-only, BCG-exposed,
  RC-ineligible/refusing, recurrent HR NMIBC
  NCT06211764

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