SunRISe-2: A Phase 3, Multicenter, Randomized Study Evaluating the Efficacy of TAR-200 in Combination With Cetrelimab Versus Chemoradiotherapy in Patients With Muscle-Invasive Bladder Cancer

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Disclosures

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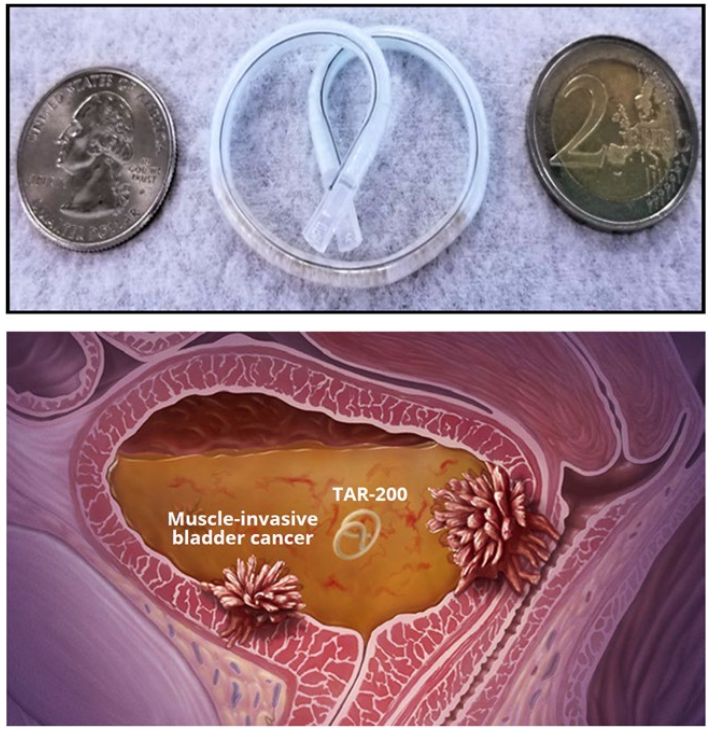
TAR-200 Is Designed to Address the Unmet Need in Patients With Muscle-Invasive Bladder Cancer

- Patients with MIBC often have poor prognosis and are at high risk of death[1-3]
  - For patients ineligible to or refusing RC, CRT is the recommended standard of care
  - Both CRT and RC are associated with high treatment burden, toxicity, and impact QOL
- TAR-200 is an intravesical targeted releasing system designed for enabling the sustained release of gemcitabine into the bladder[4,5]
- SunRISe-2 (NCT04658862) is a phase 3 clinical study designed to evaluate the efficacy and safety of intravesical TAR-200 plus cetrelimab, an investigational immunoglobulin G4 anti–PD-1 antibody, versus concurrent CRT in patients with MIBC who are ineligible for or refuse RC

TAR-200 is designed for continuous local delivery of gemcitabine to tumors within the bladder[4,5]



CRT, chemoradiotherapy; MIBC, muscle invasive bladder cancer; PD-1, programmed death ligand-1; QOL, quality of life; RC, radical cystectomy.

1. Chang SS, et al. *J Urol.* 2017;198:552-559. 2. NCCN Clinical Practice Guidelines in Oncology. Bladder Cancer. Version 1. 2024. 3. Tyson MD, Barocas DA. *Urol Clin North Am.* 2018;45:249-256.
4. Daneshmand S, et al. *Urol Oncol.* 2022;40:344.e1-344.e9. 5. Tyson MD, et al. *J Urol.* 2023:209:890-900.

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SunRISe-2 (NCT04658862) Is a Phase 3, Open-Label, Multicenter, Randomized Study

Key eligibility criteria

Inclusion criteria

- Patients with MIBC
- Ineligible for or had refused RC
- ECOG PS 0, 1, or 2
- Normal thyroid function per investigator assessment
- Adequate bone marrow, liver, and renal function

Exclusion criteria

- Urothelial carcinoma or histological variant at any site outside of the urinary bladder[a]
- Diffuse CIS based on cystoscopy and biopsy
- Evidence of cT4b, or N1-3, or M1 disease
- Bladder perforation during diagnostic cystoscopy unless healed prior to randomization

1:1
(N≈550)
R

TAR-200 (intravesical)
(n≈275)
Q3W (21-day indwelling) for first 18 weeks and from Week 24 Q12W through Study Year 3
+
Cetrelimab (IV)

Chemoradiotherapy
(n≈275)
Investigator's choice of chemotherapy
Cisplatin IV (QW for 4-6 weeks) –*or*–
gemcitabine IV (BIW for 4-6 weeks) as SOC
+
Radiation therapy
Conventional (64 Gy, bladder only) for up to 6.5 weeks –*or*–
hypo-fractionated (55 Gy, bladder only) for up to 4 weeks

Primary end point

Bladder intact event-free survival[b]

Secondary end points

- Metastasis-free survival[c]
- Overall survival[d]
- Overall response rate[e]
- Safety and tolerability

BI-EFS, bladder intact, event-free survival; BIW, twice weekly; CIS, carcinoma in situ; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; QW, every week; Q3W, every 3 weeks; Q12W, every 12 weeks; R, randomization; RECIST, Response Evaluation Criteria In Solid Tumors; SOC, standard of care.
[a]Ta/T1/CIS of the upper urinary tract (including renal pelvis and ureter) is allowable if treated with complete nephroureterectomy >24 months prior to study. [b]Time from randomization to first BI-EFS event, including histologically proven MIBC,
clinical evidence of nodal or metastatic disease (per RECIST 1.1), RC, or any-cause death. [c]Time from randomization to first radiologic evidence of metastatic disease (per RECIST 1.1) or any-cause death. [d]Time from randomization to death.
[e]Proportion of patients who achieved a complete response or partial response.

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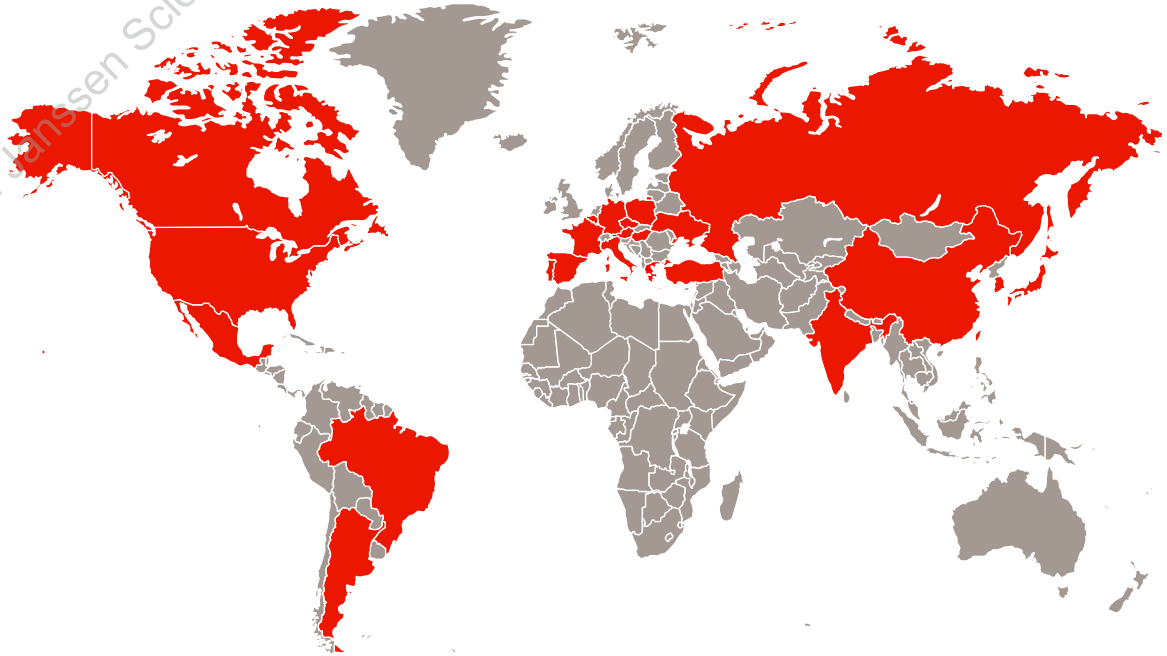
SunRISe-2 Is Currently Open and Enrolling Patients

- The SunRISe-2 study opened for enrollment on December 7, 2020, with 770 patients screened and 382 patients randomized as of April 24, 2024
- SunRISe-2 has recruited patients from Argentina, Austria, Belgium, Brazil, Canada, China (including Taiwan), Czechia, France, Germany, Greece, Hungary, India, Italy, Japan, Mexico, Poland, Portugal, Russia, South Korea, Spain, Turkey, Ukraine, and the United States
- Primary completion is expected in December 2026

SunRISe-2 is recruiting patients at 176 sites across 23 countries



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

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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
  Presented here
- **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

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