

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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<https://www.congresshub.com/Oncology/AUA2024/TAR-200/Porten>

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Disclosures

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Many Patients With HR NMIBC Recur or Progress After BCG Treatment

- **More than 75%** of newly diagnosed bladder cancers are non–muscle-invasive¹
 - Between 20% to 46% of patients with HR NMIBC experience disease recurrence after BCG treatment²⁻⁵
- Additional BCG is **not effective in early recurrences** (within 1 year) and is **not recommended by guidelines**⁶⁻⁸
- Standard of care for early BCG-unresponsive recurrence (within 1 year) of papillary-only HR NMIBC is RC^{7,8}
 - However, many patients either refuse or are ineligible for RC⁹
- Recently approved treatment options are **limited for patients with CIS**¹⁰⁻¹²

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

BCG, bacillus Calmette–Guérin; CIS, carcinoma in situ; HR NMIBC, high-risk non–muscle-invasive bladder cancer; RC, radical cystectomy.

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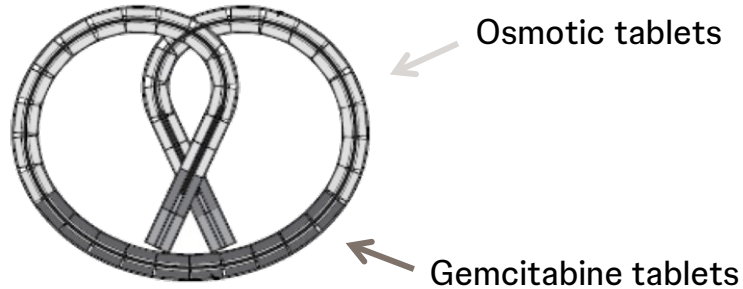
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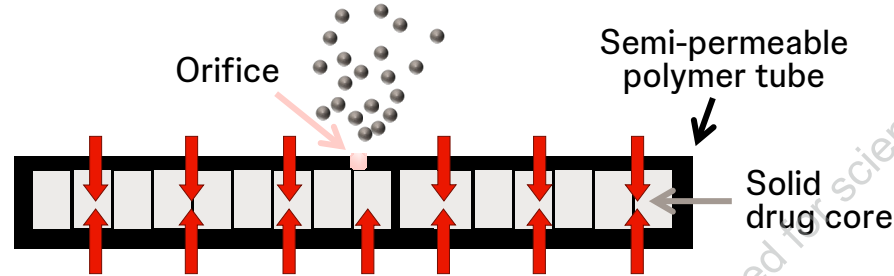


TAR-200 Is a Novel Targeted Releasing System Designed for Sustained Gemcitabine in the Bladder^{1,2}

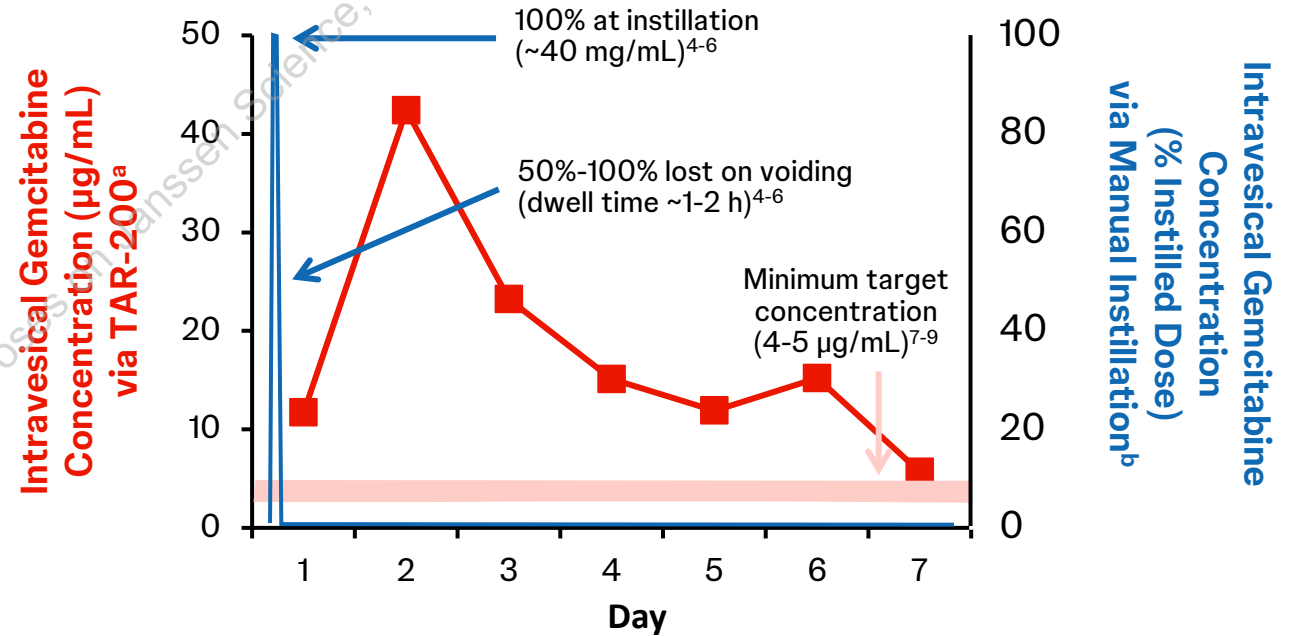
TAR-200 Mini-tablet Design



TAR-200 Osmotic System



Gemcitabine Urine Concentrations Over 7 Days: TAR-200 Delivery³ vs Current Intravesical Methods⁴⁻⁶



Interim data from SunRISe-1 (NCT04640623) support further investigation of **TAR-200 monotherapy** in patients with **BCG-unresponsive HR NMIBC¹⁰**

^aEstimated clinical concentrations based on miniature pig pharmacokinetics.³

^bPatients received instilled doses of 500-2000 mg in 50-100 mL,⁴ 2000 mg in 50 mL,⁵ or 2000 mg in 50-100 mL.⁶

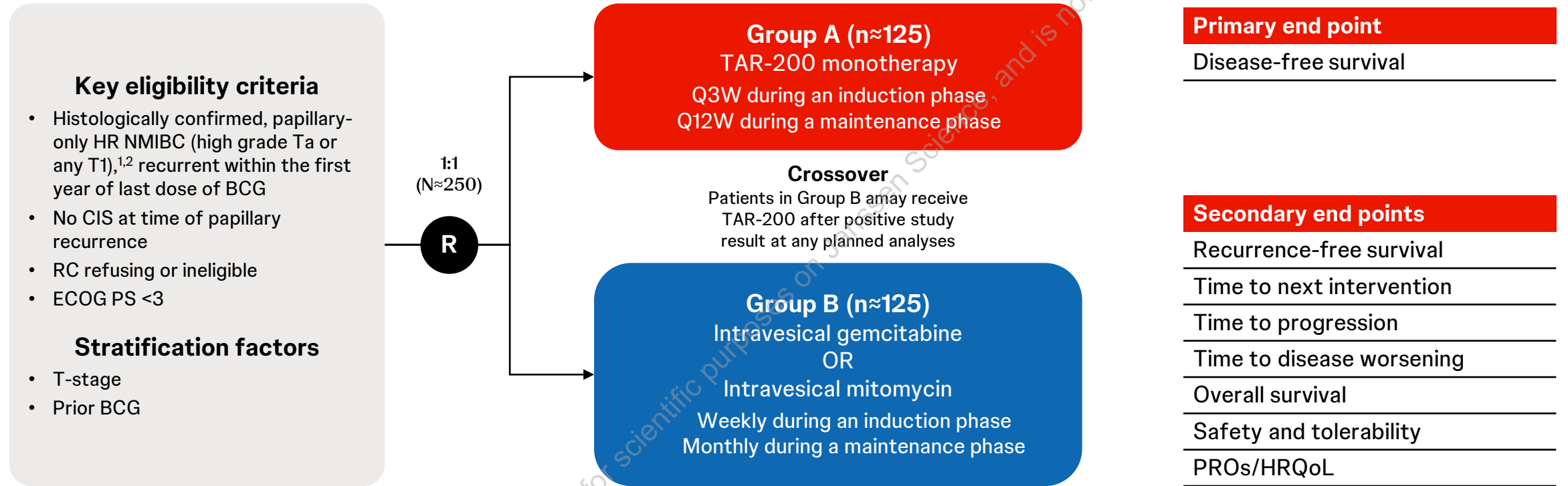
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SunRISe-5 (NCT06211764) Is an Open-Label, Multicenter Phase 3 Study



- 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-only HR NMIBC recurrent after BCG therapy who refuse or are unfit for RC

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

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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 1 year after at least 5 of 6 doses of BCG (adequate induction)**

Definition of Minimum Prior BCG Therapy in the SunRISe-5 Target Population

	Minimum BCG therapy	Timing of recurrence
BCG-unresponsive¹	Adequate Induction (5 of 6 doses) AND either 2 of 3 doses of Maintenance OR 2 of 6 doses of second Induction	HG T1 disease at first disease assessment after Induction OR HG Ta/any T1 disease within 6 months
BCG-experienced <i>Does not meet BCG-unresponsive definition</i>	Received Adequate Induction (5 of 6 doses) with or without Maintenance therapy	Recurred with HG Ta/any T1 disease within 12 months

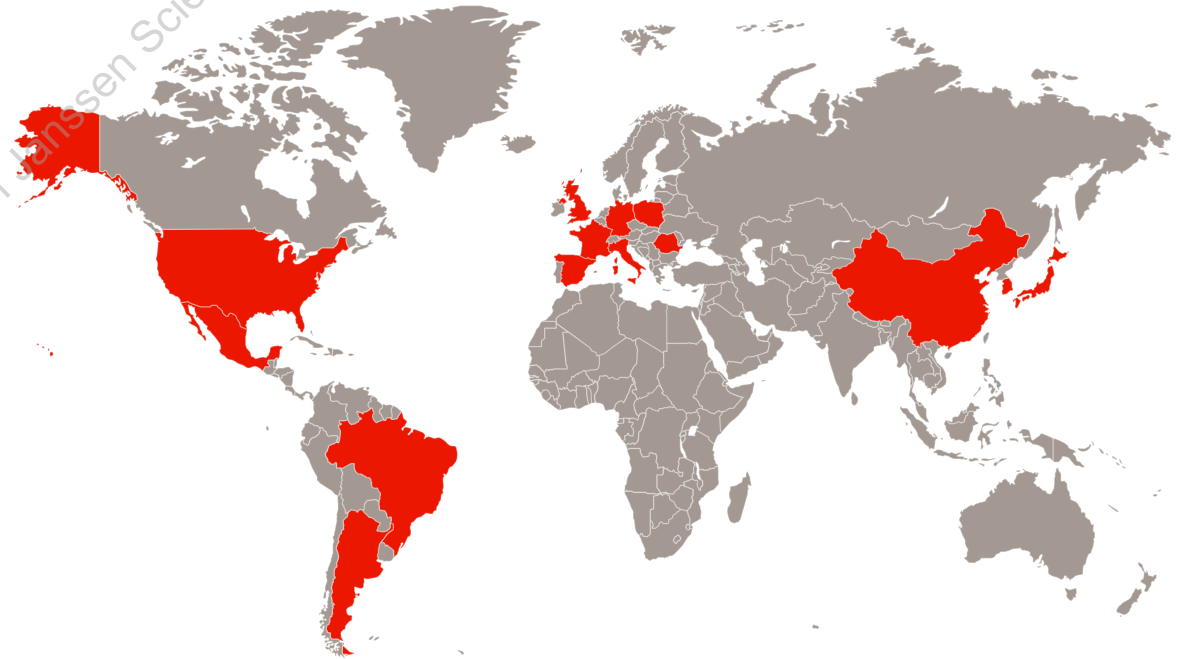
1. US Food and Drug Administration. "BCG-unresponsive nonmuscle invasive bladder cancer: developing drugs and biologics for treatment guidance for industry." Center for Drug Evaluation and Research (2018).



SunRISe-5 Is Currently Open and Enrolling Patients

- Site activations and patient screenings have launched as of April 18, 2024
- SunRISe-5 is currently recruiting in Argentina, Brazil, China, France, Germany, Italy, Japan, Mexico, Poland, Romania, South Korea, Spain, the United Kingdom, and the United States

**Enrollment is planned at 128 sites
across 14 countries**



Acknowledgments

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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
- **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](#)

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