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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Current Status

The phase 3 SunRISe-5 study opened for enrollment in March 2024. As of November 5, 2024, 105 patients have been randomized, and recruitment is ongoing at ~120 sites

Registration and Contact Information

SunRISe-5 is registered on ClinicalTrials.gov as NCT06211764

For questions or information about enrollment, please contact Sumeet Bhanvadia, MD, the Study Responsible Physician, at sbhanvad@its.jnj.com

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Poster

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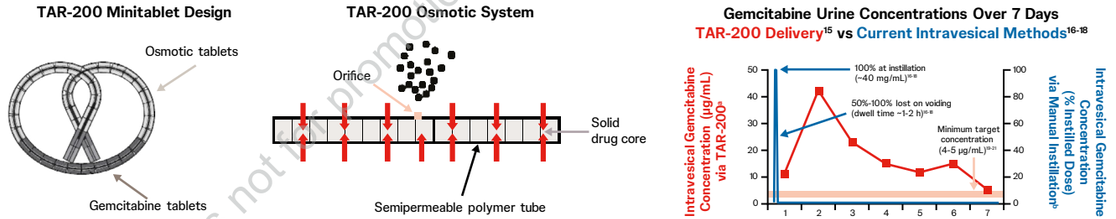
Disclosures
Dr Porten is an advisory board member for Photocure and Fergene, is a consultant for Photocure and Stryker, and has received research funding from Oncuria and Photocure.

Introduction

- More than 75% of newly diagnosed bladder cancers are non–muscle-invasive (NMIBC)[1]
  - Between 20% and 46% of patients with high-risk (HR) NMIBC experience disease recurrence after bacillus Calmette-Guérin (BCG) treatment[2-5]
- Additional BCG is not effective in early recurrences (within 1 year) and is not recommended by guidelines [6,7]
- Standard of care for early BCG-unresponsive recurrence (within 1 year) of papillary-only HR NMIBC is radical cystectomy (RC) [7]
  - However, many patients either refuse or are ineligible for RC [8]
- Recently approved treatment options are limited for patients with carcinoma in situ (CIS)[9-11]
- There is a high unmet need to develop bladder-sparing, localized treatments for patients with papillary-only recurrent HR NMIBC
- TAR-200 is a novel gemcitabine intravesical releasing system designed for sustained gemcitabine in the bladder[12,13] (Figure 1)
- Interim data from SunRISe-1 (NCT04640623) support further investigation of TAR-200 monotherapy in patients with BCG-unresponsive HR NMIBC[14]

Figure 1: TAR-200 design and sustained release of gemcitabine in the bladder

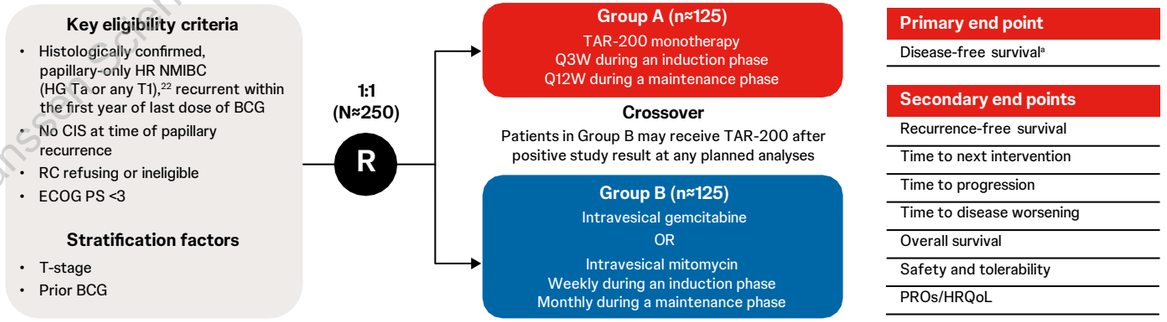


[a]Estimated concentrations based on miniature pig pharmacokinetics.[15] [b]Patients received instilled doses of 500-2000 mg in 50-100 mL,[16] 2000 mg in 50 mL,[17] or 2000 mg in 50-100 mL.[18]

Methods

- SunRISe-5 (NCT06211764) is an open-label, multicenter phase 3 study (Figure 2)
- The study will evaluate whether TAR-200 will prolong disease-free survival compared with intravesical chemotherapy in patients with papillary-only HR NMIBC that recurs after BCG therapy who refuse or are unfit for RC
- 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) (Table 1)
- The primary end point is disease-free survival

Figure 2: SunRISe-5 study design



ECOG PS, Eastern Cooperative Oncology Group performance status; HRQoL, health-related quality of life; PRO, patient-reported outcome; R, randomized; Q3W, every 3 weeks; Q12W, every 12 weeks.
[a]Disease-free survival is defined as time from randomization to first recurrence of HR NMIBC (high-grade [HG] Ta, any T1, or CIS), progression, or any-cause death, whichever occurs first.

Table 1: Definition of minimum prior BCG therapy in the SunRISe-5 target population

	Minimum BCG therapy	Timing of recurrence
BCG unresponsive[23]	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 *Does not meet BCG-unresponsive definition*	Received adequate induction (5 of 6 doses) with or without maintenance therapy	Recurred with HG Ta/any T1 disease within 12 months

Figure 3: Enrollment is ongoing at ~120 sites across 14 countries

Global Enrollment for SunRISe-5

- SunRISe-5 is currently open and enrolling patients
- First global site opened March 29, 2024
  - As of November 5, 2024, 98% of sites are activated, and 42% of the target population has been randomized
- SunRISe-5 is currently recruiting in Argentina, Belgium, Brazil, China, France, Germany, Italy, Japan, Poland, Romania, South Korea, Spain, the United Kingdom, and the United States (Figure 3)

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