MoonRISe-1: Phase 3 Study of TAR-210, an Erdafitinib Intravesical Releasing System, Versus Intravesical Chemotherapy in Patients With *FGFR*-Altered Intermediate-Risk Non–Muscle-Invasive Bladder Cancer

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Current Status

The phase 3 MoonRISe-1 study opened for enrollment in April 2024. As of November 6, 2024, 82 patients have been randomized, and recruitment is ongoing at 163 sites

Registration and Contact Information

MoonRISe-1 is registered on ClinicalTrials.gov as NCT06319820

For questions or information about enrollment, please contact Angela Girvin, MD, the Study Responsible Physician, at RA-MoonRISe1Clinical@its.jnj.com

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Poster

https://www.congresshub.com/Oncology/SUO2024/ErdaRIS/Li

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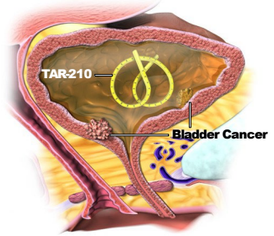
Disclosures

R Li has served as a scientific advisor/consultant for Bristol Myers Squibb, Merck, Ferring, Fergene, ArquerDiagnostics, Urogen Pharma, CG Oncology, and Lucence; has served on the clinical trial protocol committee for CG Oncology; has received research support from Predicine, Veracyte, CG Oncology, and Valar Labs.

Introduction

- Despite available treatment options for patients with intermediate risk (IR) non–muscle-invasive bladder cancer (NMIBC), recurrence rates remain high, underscoring the need for effective therapies[1]
- Fibroblast growth factor receptor (*FGFR*) alterations are prevalent in ~50% to 80% of low-grade NMIBC and may function as oncogenic drivers[2-4]
- Erdafitinib is a selective pan-FGFR tyrosine kinase inhibitor[5]
  - Oral erdafitinib (Balversa®) is approved in the United States to treat adults with locally advanced or metastatic urothelial carcinoma with susceptible *FGFR3* alterations following progression on or after at least 1 prior systemic treatment, with additional approvals across geographies[6-9]
- Oral erdafitinib demonstrated clinical efficacy in high-risk (HR) and IR NMIBC populations, but was limited by challenging systemic toxicities[10-12]
  - In an interim analysis of THOR-2 Cohort 3, 15/18 patients with *FGFR*-altered IR NMIBC had complete response (CR; 83%), with a median duration of response (DOR) of 12.8 months[13]
- TAR-210 is a novel erdafitinib intravesical releasing system designed for sustained local delivery of erdafitinib over 3 months in the bladder (Figure 1)[14]
- MoonRISe-1 (NCT06319820) is an open-label, multicenter, randomized phase 3 study to evaluate the efficacy and safety of TAR-210 versus intravesical chemotherapy in patients with *FGFR*-altered, low-grade IR NMIBC

Figure 1: TAR-210 is a novel erdafitinib intravesical releasing system designed for sustained local delivery of therapy over 3 months in the bladder

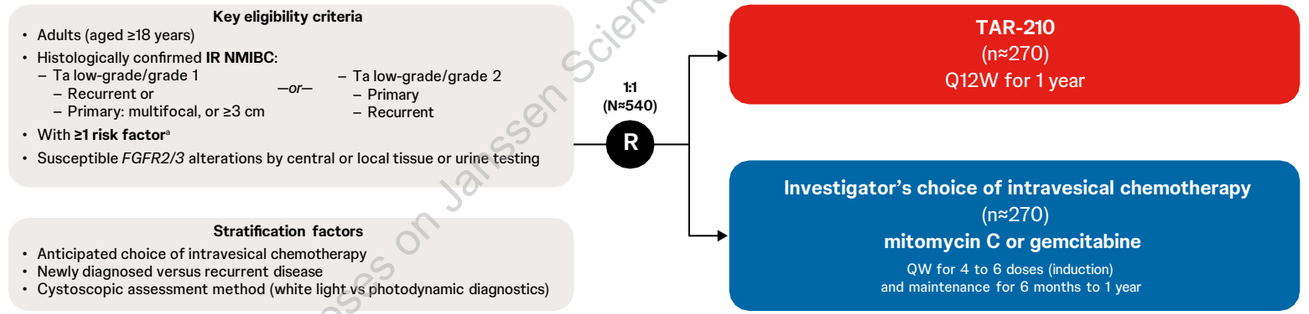


In a first-in-human study, TAR-210 was well tolerated, with promising clinical activity in *FGFR*-altered **HR NMIBC (recurrence-free survival rate: 82%)** and **IR NMIBC (CR rate: 87%)**[14]

TAR-210 is placed using a urinary placement catheter in a brief in-office procedure

Methods

Figure 2: MoonRISe-1 study design



QW, every week; Q12W, every 12 weeks; R, randomized.
[a]Risk factors include multiple Ta low-grade tumors, tumors >3 cm, early (≤1 year) recurrence, frequent (>1 per year) recurrences, or recurrence after intravesical chemotherapy received >6 months prior.
[b]Disease-free survival defined as time from randomization to first documented recurrence of any-grade NMIBC, disease progression, or death from any cause, whichever occurs first.

Study Design of MoonRISe-1

- Eligible patients with histologically confirmed IR NMIBC (N≈540) with susceptible *FGFR2/3* alterations will be randomized 1:1 to receive TAR-210 or investigator's choice of intravesical chemotherapy, mitomycin C, or gemcitabine (Figure 2)
- All visible papillary disease must be fully resected prior to randomization
- The primary end point is disease-free survival
- Assessments of recurrence or progression include urine cytology, cystoscopy, for-cause transurethral resection of bladder tumor (TURBT) or biopsy of bladder lesions, ultrasound, and urography
- The follow-up phase for patients meeting the primary end point is up to ≈5 years

Global Enrollment for MoonRISe-1

- The MoonRISe-1 study opened for enrollment on April 10, 2024
- Recruitment is planned at 200 sites (Figure 3)
- As of November 6, 2024, 82 patients have been randomized, and recruitment is ongoing at 163 sites

Figure 3: Enrollment is ongoing at 163 sites in 19 countries across 4 continents

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