SunRISe-5 Trial In Progress: 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

Porten [1], S. Bhanvadia [2], S. Najmi [3], H. Sweiti [4], J. Maffeo [5], K. Stromberg [3], B. Pradere [6], N. Vasdev [7]

(1) University of California, San Francisco, CA - United States, (2) Janssen Research & Development, Los Angeles, CA - United States, (3) Janssen Research & Development, Raritan, NJ - United States, (4) Janssen Research & Development, Spring House, PA - United States, (5) Janssen Research & Development, Lexington, MA - United States, (6) Department of Urology, UROSUD, La Croix Du Sud Hospital, Quint-Fonsegrives - France, (7) Department of Urology, Lister Hospital (ENHT NHS Trust), Stevenage - United Kingdom

Objective:

Efficacious therapies for patients with high-risk non–muscle-invasive bladder cancer (HR NMIBC) whose disease recurs after bacillus Calmette-Guérin (BCG) therapy are limited. TAR-200 is a novel intravesical drug delivery system designed to provide local, sustained release of gemcitabine within the bladder. SunRISe-5 (NCT06211764) is a randomized, open-label, multicenter phase 3 study that evaluates the safety and efficacy of TAR-200 compared with intravesical chemotherapy in patients with papillary-only HR NMIBC that recurs within the first year of BCG treatment who either refuse or are ineligible for radical cystectomy (RC).

Methods:

Eligible patients are aged ≥18 years, have an ECOG performance status of 0-2, and were diagnosed within ≤90 days of informed consent with histologically confirmed recurrent, papillary-only HR NMIBC (defined as high-grade Ta or any T1, no carcinoma in situ) with a last dose of BCG ≤12 months, who are ineligible for or who have elected not to undergo RC. Patients will be stratified based on T stage and prior BCG. 250 patients will be randomized 1:1 to receive TAR-200 every 3 weeks for an induction phase and every 12 weeks during a maintenance phase or to receive investigator's choice of mitomycin C or gemcitabine weekly during induction and monthly during the maintenance phase. The primary end point is disease-free survival. Secondary end points include recurrence-free survival, time to next intervention, time to disease worsening, time to progression, overall survival, safety and tolerability, and patient-reported health-related quality of life outcomes. This trial is enrolling patients across 4 sites in the UK.

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