



What do these results mean for individuals with bladder cancer, for whom previous treatment with BCG did not work?

- Treatment with TAR-200 was effective (ie, cancer was undetectable/complete response achieved) in 82% of participants
- More than half of participants (53%) who achieved a complete response responded to treatment for at least 1 year
- Treatment with TAR-200 was generally well tolerated, with most side effects being mild and side effects that led to stopping treatment being infrequent
- Participants' well-being and ability to do physical activity were also maintained
- No treatment-related deaths occurred



What was the purpose of this study?

- The purpose of this ongoing study, called SunRISe-1, is to test a new treatment called TAR-200 in patients with a type of bladder cancer (high-risk non–muscle-invasive) where another treatment, bacillus Calmette–Guérin (BCG), has not worked
- TAR-200 is a unique drug-releasing system that slowly releases the chemotherapy drug gemcitabine directly in the bladder
- The study aims to find out how effective TAR-200 is in these patients



How was the study carried out?



85 participants were included



Participants were given TAR-200 **once every 3 weeks** for **24 weeks**



Followed by **once every 12 weeks** for **72 weeks**, for a **total of 96 weeks**

- ✓ Doctors checked the participants regularly using several methods, including examination of inside of the bladder with a lens (cystoscopy), urine analysis (cytology), and/or a biopsy to see how well the treatment was working
- ✓ Side effects directly related to the treatment and the well-being of participants were also monitored

TAR-200 Monotherapy in Patients With Bacillus Calmette–Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer Carcinoma in Situ: 1-Year Durability and Patient-Reported Outcomes From SunRISe-1

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What were the results?

- Treatment with TAR-200 helped 82% of participants achieve a complete response (ie, the cancer was undetectable by scientific measurements including cystoscopy, cytology, biopsy, and imaging) and more than half of the participants (53%) who achieved a complete response responded to treatment for at least 1 year
- TAR-200 led to mild and manageable side effects and participants' well-being was maintained

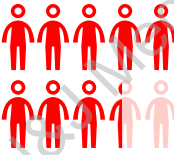


Who was in the study?

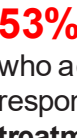
- Of the **85** participants:
- All had high-risk non–muscle-invasive bladder cancer with a form called carcinoma in situ, where previous treatment with BCG was not effective
 - All had their bladder cancer return within 12 months of their last BCG treatment (more than 12 months in 2 participants)
 - **97%** declined bladder removal, and the rest could not have their bladder removed
 - **80%** were male and **20%** were female
 - **87%** were White, **9%** were Asian and **2%** were Black or African American
 - More than two thirds (**67%**) smoked or had smoked previously
 - Median age was **71 years**



How well did TAR-200 work?



82% of participants achieved a **complete response** (ie, cancer was not detectable) following treatment



53% of participants who achieved a complete response **responded to treatment** for at least **12 months**



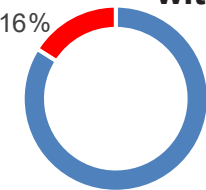
The median time that cancer remained undetectable was **26 months**

Measure of participant well-being:

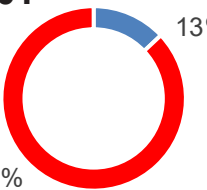
Treatment with TAR-200 helped participants maintain their quality of life and ability to do physical activities—based on a questionnaire that they completed



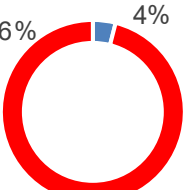
What were the side effects of treatment with TAR-200?



84% of participants experienced at least 1 side effect of any severity



13% of participants experienced at least 1 side effect that was grade 3 or higher

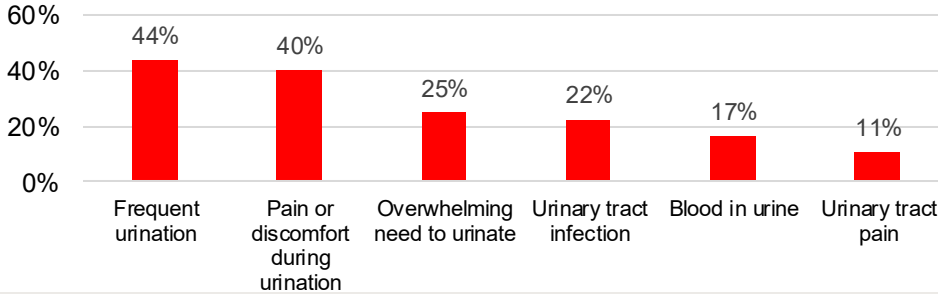


4% of participants experienced side effects that led to stopping treatment

99% of TAR-200 insertions were successful

No treatment-related deaths were reported

Most common side effects of any severity in more than 10% of participants



Glossary of Terms

Bacillus Calmette–Guérin (BCG)	A vaccine primarily used against tuberculosis, also used in bladder cancer treatment	TAR-200	A drug-releasing system placed into the bladder that was designed to provide continued delivery of gemcitabine (in the bladder)	Median	The middle number in a sequence of numbers ordered from lowest to highest	Grade	A grading system from 1 to 5 is used to describe the severity of a side effect. Side effects graded 1 or 2 are considered mild to moderate. Side effects graded 3 or above are considered serious and need immediate medical attention
High-risk non–muscle-invasive bladder cancer (HR NMIBC)	A type of bladder cancer that has not invaded the muscle layer but has a high risk of doing so	Carcinoma in situ	Cancer cells present in the lining of the bladder that have a flat appearance and have not spread to other organs	Gemcitabine	A chemotherapy treatment		



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