

## A Phase 3, Open-Label, Multi-Center, Randomized Study Evaluating the Efficacy and Safety of TAR-200 in Combination with Cetrelimab or TAR-200 Alone Versus Intravesical Bacillus Calmette-Guerin (BCG) in Participants with BCG-naive High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- diagnosis of high grade non-muscle invasive bladder cancer (HR-NMIBC) (high-grade Ta, any T1 or carcinoma in-situ [CIS]) - have not received Bacillus Calmette Guerin (BCG) - cancer must be surgically removed - able to walk and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours

#### Exclusion Criteria:

- more extensive bladder cancer (muscle invasive, locally advanced, nonresectable, or metastatic urothelial carcinoma (that is, greater than and equal to [ $\geq$ ] T2)) - history of clinically significant polyuria with recorded 24-hour urine volumes greater than 4000 milliliters (mL) - Indwelling catheters are not permitted; however, intermittent catheterization is acceptable - additional exclusion criteria (study staff will review)

### Conditions & Interventions

#### Interventions:

Biological: BCG Vesiculture, Biological: Cetrelimab, Drug: TAR-200

#### Conditions:

Cancer

#### Keywords:

Clinics and Surgery Center (CSC), Bladder Cancer

### More Information

**Description:** The purpose of this study is to compare the effects (both good and bad) of an investigational drug delivery system (TAR-200) in combination with cetrelimab or TAR-200 alone to the effects of study drug comparator intravesical (medicine that is put directly into the bladder instead of being taken like a pill or put into veins) BCG in patients with HR-NMIBC. Cetrelimab is a medicine that may treat certain cancers by working with the immune system (it is also known as immunotherapy). Immunotherapy is the use of medicines to help a person's own immune system recognize and destroy cancer cells.

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#### IRB

**Number:** STUDY00019140

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