

## A Phase II Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) and Pembrolizumab in Combination with Other Investigational Agents in Subjects with High-risk Non-muscle-Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG) Therapy

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy volunteers

#### Inclusion Criteria:

- confirmed diagnosis of high risk non-muscle-invasive (T1, high grade Ta and / or carcinoma in situ) transitional cell carcinoma of the bladder - tumor has been completely removed with bladder surgery - BCG-unresponsive high risk non-muscle-invasive bladder cancer after treatment with adequate BCG therapy - ineligible for radical cystectomy or refusal of radical cystectomy - able to care for self, up and about for at least half of the day - participants of child bearing age must be willing to use effective birth control

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#### Exclusion Criteria:

- received intravesical chemotherapy or immunotherapy from the time of most recent cystoscopy / Transurethral Resection of Bladder Tumor (TURBT) - active autoimmune disease that has required systemic treatment in the past 2 years - active infection requiring systemic therapy - pregnant or breast feeding - contact study staff for additional study eligibility criteria

### Conditions & Interventions

#### Conditions:

Cancer, Kidney, Prostate & Urinary

#### Keywords:

Clinics and Surgery Center (CSC), Bladder Cancer

### More Information

**Description:** This trial will evaluate other treatment options for high-risk NMIBC patients who were unresponsive to Bacillus Calmette Guerin (BCG therapy). We are studying two different drugs in combination with pembrolizumab. Participants will receive up to 35 doses of the trial drug and have tumor assessments for about 2 years. This will be followed by treatment tumor assessment for another 3 years for a total trial duration of 5 years.

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**Principal Investigator:** Joseph Zabell

#### IRB

**Number:** 1604M87002

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