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

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.
Study Contact: Skylar Mast - smast@umn.edu
Principal Investigator: Joseph Zabell
Phase: PHASE2
IRB Number: 1604M87002