A Phase 2, Open-Label, Multi-Center, Randomized Study of TAR-200 in Combination with Cetrelimab and Cetrelimab Alone in Participants with Muscle-Invasive Urothelial Carcinoma of the Bladder who are Scheduled for Radical Cystectomy and are Ineligible for or Refusing Platinum-Based Neoadjuvant Chemotherapy

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosed with urothelial cancer of the bladder within past 120 days - restricted in strenuous physical activity but able to walk and carry out work of a light or sedentary nature, e.g., light house work, office work - thyroid function tests within normal range or stable on hormone supplement

Exclusion Criteria:

- have received prior systemic chemotherapy, targeted small molecule therapy, or radiation therapy within prior 2 weeks - prior systemic chemotherapy for urothelial cell carcinoma of the bladder - additional criteria apply (study staff will review)

Conditions & Interventions

Interventions:
Biological: Cetrelimab, Drug: TAR-200
Conditions:
Cancer
Keywords:
Clinics and Surgery Center (CSC), Bladder Cancer, Cystectomy, Urinary Bladder Neoplasms

More Information

Description: This study investigates a new treatment (TAR-200) for Muscle-Invasive Urothelial Carcinoma (bladder cancer). It assesses whether TAR-200 + Cetrelimab (experimental drug), is effective for patients scheduled for bladder removal surgery who can't undergo standard chemotherapy. The study compares two groups: one receiving TAR-200 + Cetrelimab, and the other receiving only Cetrelimab. The goal is to determine if this combination can provide an alternative treatment option for these patients with bladder cancer.
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