A Study of Intravesical BCG in Combination With ALT-803 in Patients With Non-Muscle Invasive Bladder Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria 1. Histologic confirmation of non-muscle invasive bladder cancer of the transitional cell carcinoma high-grade subtype (mixed histology tumors allowed i transitional cell histology is predominant histology). 1. Cohort A: Histologically confirmed CIS (with or without Ta/T1 disease); Cohort B: Histologically confirmed high-grade papillary disease (Ta/T1 only). 2. Patients are eligible if the diagnostic biopsy was done within 3 months of treatment start and a cystoscopy demonstrating no resectable disease was done within 6 calendar weeks (inclusive of 48 days) of treatment start (residual CIS is acceptable; patients with T1 disease must undergo repeat resection if muscularis propria is not present in each biopsy sample). Patients with high-grade Ta and/or T1 disease should have complete resection before study treatment. 3. Upper tract imaging within 6 months prior to study entry must not be suspicious for upper tract malignancy. 2. Currently eligible for intravesical BCG therapy. 3. Age ≥ 18 years. 4. Performance status: ECOG performance status of 0, 1, or 2. 5. BCG-naive disease as defined as either of the following: 1. Have not received prior intravesical BCG; or 2. Previously received BCG, but stopped receiving more than 3 years before date of randomization. 6. Laboratory tests performed within 21 days of treatment start: 1. Absolute lymphocyte count ≥ Institutional lower limit of normal 2. Absolute neutrophil count (AGC/ANC) ≥ 1,000/µL 3. Platelets ≥ 100,000/µL \[Patients may be transfused to meet this requirement\] 4. Hemoglobin ≥ 8 g/dL \[Patients may be transfused to meet this requirement\] 5. Calculated glomerular filtration rate (GFR*) \>40 mL/min or Serum creatinine ≤ 1.5 x ULN 6. Total bilirubin ≤ 2.0 X ULN 7. AST, ALT, ALP ≤ 3.0 X ULN 7. Adequate pulmonary function without any clinical sign of severe pulmonary dysfunction. PFT \> 50% FEV1 if clinically indicated by the investigator. 8. Negative serum pregnancy test if female and of childbearing potentia (non-childbearing is defined as greater than one year postmenopausal or surgically sterilized). 9. Female participants of childbearing potential must adhere to using a medically accepted method of birth control prior to screening and agree to continue its use during the study or be surgically sterilized (e.g., hysterectomy or tubal ligation) and males must agree to use barrier methods of birth control while on study. 10. Provide signed informed consent and HIPPA authorization and agree to comply with all protocol-specified procedures and follow-up evaluations. * using the following Cockcroft-Gault equation to calculate the eGFR for this study: eGFR in mL/min = {(140-age in years) x (weight in kg) x F}/(serum creatinine in mg/dL x 72) Where F =1 if male; and 0.85 if female Exclusion Criteria 1. Prior BCG treatment or known hypersensitivity to BCG. Patients who have received more than a single-dose post-operative treatment of mitomycin-C or gemcitabine following the most recent screening TURBT/biopsy are excluded. 2. Concurrent use of other investigational agents (not including FDA-authorized drugs for the prevention and treatment of COVID-19). 3. History of or evidence of muscle-invasive, locally advanced, metastatic and/or extravesical bladder cancer or any other cancer within the past 5 years, except: adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, adequately treated stage 1 or 2 cancer from which the patient is currently in complete remission, or stable prostate cancer (under active surveillance or hormone control). 4. Symptomatic congestive heart failure (CHF), NYHA (New York Heart Association) Class III or IV or other clinical signs of severe cardiac dysfunction. 5. Severe/unstable angina pectoris, or myocardial infarction within 6 months prior to study entry. 6. History or evidence of uncontrollable CNS disease. 7. Known HIV-positive. 8. Active systemic infection requiring parenteral antibiotic therapy. All prior infections must have resolved following optimal therapy. 9. Concurrent febrile illness, active urinary tract infection, active tuberculosis, a history of hypotension or anaphylactic reactions. 10. Ongoing chronic systemic steroid therapy required (\>10 mg oral prednisone daily or equivalent). 11. Women who are pregnant or nursing. Female patients of childbearing potential must have a negative pregnancy test and must adhere to using a medically acceptable method of birth control prior to screening and agree to continue its use during the study and for 30 days after the last dose of study drug, or be surgically sterilized (e.g., hysterectomy or tubal ligation). Women of childbearing potential are defined as any female who has experienced menarche and who is NOT permanently sterile or postmenopausal. Postmenopausal is defined as 12 consecutive months with no menses without an alternative medical cause. Males must agree to use barrier methods of birth control while on study and for 90 days post last dose of study drug. 12. Psychiatric illness/social situations that would limit compliance with study requirements. 13. Other illness that in the opinion of the investigator would exclude the patient from participating in this study.

Conditions & Interventions

Interventions:

BIOLOGICAL: BCG+N-803(50mg BCG/ Instillation+ N-803(400 µg/instillation).), BIOLOGICAL: BCG(50mg/Instillation)

Conditions:

Non-muscle Invasive Bladder Cancer

Keywords:

antitumor, BCG, bladder cancer, cancer, immunotherapy, instillation, interleukin-15, intravesical, naive, non-muscle invasive, transitional cell carcinoma, ALT-803, N-803

More Information

Contact(s): Paula Bradshaw, MSN, MBA, RN - paula.bradshaw@immunitybio.com

Principal Investigator:

Phase: PHASE1

IRB

Number:

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