RESQ133A-NMIBC: PHASE 1/2 CLINICAL TRIAL OF INTRAVESICAL RECOMBINANT MYCOBACTERIUM (rMBCG) IN PARTICIPANTS WITH NMIBC ELIGIBLE TO RECEIVE INTRAVESICAL TICE BCG

Study Number:	ResQ133A-NMIBC
IND Sponsor:	ImmunityBio, Inc.
IND Number:	031376
Sponsor Contacts:	
Clinical Development and Operations	Anjali Malhotra, DRSc Senior Vice President, Clinical Development and Quality Assurance ImmunityBio, Inc 9920 Jefferson Blvd Culver City, CA 90232 Email: Anjali.Malhotra@ImmunityBio.com Cell Phone: +1-310-613-9651
Medical Monitor **(For medical questions/emergencies)**	Bruce Brown, MD Senior Vice President, Medical Affairs ImmunityBio, Inc 9920 Jefferson Blvd Culver City, CA 90232 Email: Bruce.Brown@ImmunityBio.com Cell Phone: +1-847-321-5699

4. PARTICIPANT ENROLLMENT AND WITHDRAWAL

4.1. Participant Eligibility

4.1.1. Inclusion Criteria

Participants must meet ALL of the following criteria for inclusion in the study:

1. Male or female participants 18 years of age or older.
2. Histologic confirmation of BCG naïve non-muscle invasive urothelial carcinoma of the bladder (mixed histology tumors allowed if urothelial histology is predominant histology) AND either i) histologically confirmed presence of NMIBC CIS (with or without Ta/T1 papillary disease) OR ii) primary or recurrent stage Ta and/or T1 papillary tumors following transurethral resection (TUR).
3. Absence of resectable disease after TURBT procedures (residual CIS acceptable; participants with T1 tumors must undergo repeat resection and biopsy [inclusive of muscularis propria] of the T1 tumor site if initial biopsy did not include muscularis propria).
4. Eastern Cooperative Oncology Group (ECOG) performance status (Appendix 1) of 0, 1, or 2.
5. Voluntary written informed consent and agreement to comply with all protocol-specified procedures and follow-up evaluations.
6. The providing physician has no access to FDA approved BCG due to shortage of TICE BCG.

4.1.2. Exclusion Criteria

Participants with ANY of the following criteria are excluded from participation in the study:

1. Life expectancy <2 years
2. Any of the following clinical laboratory values at the time of enrollment:
    a. Absolute neutrophil count (ANC) <800/μL
    b. Platelets < 50,000/μL
    c. Liver function abnormalities as indicated by ongoing hepatic enzyme elevation (aspartate aminotransferase [AST] or alanine aminotransferase [ALT]) > 2 X upper limit of normal (ULN)
    d. Renal insufficiency as indicated by a creatinine level >3 X ULN
3. History of or evidence of muscle-invasive, locally advanced, metastatic and/or extravesical bladder cancer (inclusive of the prostatic urethra); or any other cancer within the past 5 years that is progressing or requires active treatment. Exceptions are adequately treated basal cell or squamous cell skin cancer that has undergone potentially curative therapy or in situ cervical cancer; and adequately treated stage I or II cancer or stable prostate cancer from which the participant is

currently in complete remission, and is under active surveillance or hormone control.

4. Symptomatic congestive heart failure (CHF), New York Heart Association (NYHA) Class III or IV heart failure (Appendix 2) 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 central nervous system disease.
7. Active systemic infection requiring parenteral antibiotic therapy. All prior infections must have resolved following optimal therapy.
8. Concurrent febrile illness, active urinary tract infection, active tuberculosis, a history of hypotension or anaphylactic reactions.
9. Ongoing chronic systemic steroid therapy required (>10 mg oral prednisone daily or equivalent).
10. Women who are pregnant or nursing. Female participants 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 (eg, 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.
11. Participants currently receiving investigational or commercial anticancer agents or anticancer therapies other than rMBCG and supportive care therapies for active disease.
12. Concurrent use of other investigational agents (not including FDA authorized drugs for the prevention and treatment of COVID-19).
13. Other illness or condition, including laboratory abnormalities, which in the opinion of the Investigator would exclude the participant from participating in this study. This includes, but is not limited to, serious medical conditions or psychiatric illness likely to interfere with participation in the study.