

## Study Protocol Summary

Patients in each Cohort will require a set of procedures prior to study baseline.

All study patients treated will receive either N-803 plus BCG or BCG alone instillations, weekly for 6 consecutive weeks during the induction treatment period. A response assessment will be performed at Week 12 (month 3).

Patients with no disease or low-grade Ta disease at months 6, 12, 18, 24, 30, and 36 are eligible for continued maintenance treatment (3 weekly instillations) according to their assigned randomization arm.

Patients will be followed for disease recurrence, progression post-therapies, QoL and survival. Presence of low-grade Ta disease will require a TURBT procedure before instillation.

Patients with presence of disease greater than low-grade Ta will be considered a treatment failure, receive no further study treatment and be followed for disease progression post-therapies, QoL, and survival.

## Target Populations and Enrollment

**Cohort A:** The planned enrollment is for 366 patients with carcinoma in situ (CIS) disease to be randomized 1:1 via a randomization scheme.

**Cohort B:** The planned enrollment is for 230 patients with high-grade papillary disease only to be randomized 1:1 via a randomization scheme.

## About the Study

ANKTIVA® (N-803) is being studied in several clinical trials for other types of cancer including different stages of non-muscle invasive bladder cancer.

Visit: <https://clinicaltrials.gov/study/NCT02138734>

### Become an Investigator in the QUILT-2.005 study.

*Your cancer prognosis may or may not improve by taking part in the QUILT-2.005 study.*

*N-803 is investigational for this indication. Safety and efficacy have not been established by any Health Authority or Health Agency, including the FDA, for this indication.*



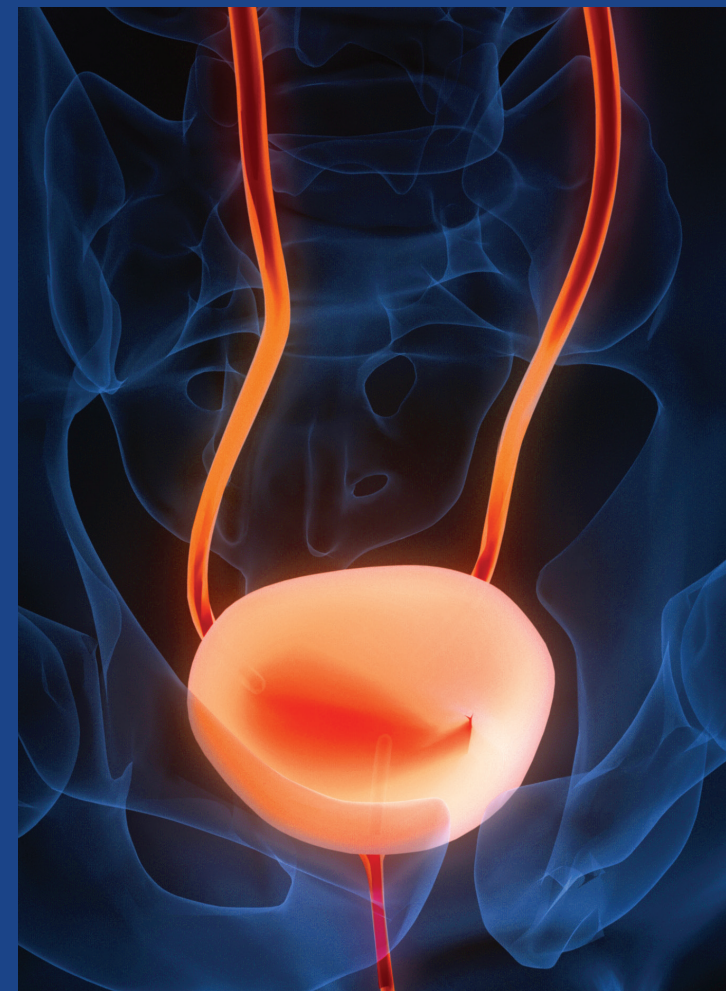
Contact ImmunityBio to learn more at **844-696-5235** or visit [immunitybio.com/open-a-trial](https://immunitybio.com/open-a-trial)



## QUILT-2.005 NCT02138734

This is an investigational trial for BCG-naïve Non-Muscle Invasive Bladder Cancer

For healthcare provider use



## Join ImmunityBio in Clinical Research

N-803 is an IL-15 receptor agonist that activates and proliferates natural killer (NK) cells, and effector and memory T cells.

### QUILT-2.005 Clinical Trial

A study is enrolling patients who have been recently diagnosed with non-muscle invasive bladder cancer (NMIBC) and have not yet received Bacillus Calmette-Guérin (BCG), or have not received BCG in the last 3 years. In this phase 2b trial, BCG naive NMIBC patients will be randomized to receive either intravesical N-803 in combination with BCG or BCG alone.

Patients will be enrolled into one of two study cohorts (Cohort A and Cohort B). These will be two independent study cohorts, evaluated separately for treatment efficacy and safety.

## Study Design

- **Carcinoma in Situ Cohort:** Complete Response (CR) Rate [Time Frame: 6 Months] will be evaluated. The Sponsor will compare the CR rate between treatment arms using cystoscopy, urine cytology and bladder biopsy if indicated.
- **Papillary Disease Cohort:** Disease Free Survival (DFS) [Time Frame: 13 Years and 3 Months] will be evaluated. The Sponsor will compare DFS between treatment arms using cystoscopy, urine cytology and bladder biopsy if indicated

## Inclusion and Exclusion

**INCLUSION CRITERIA:** Patients must meet several KEY criteria for inclusion in the study:

1. Histologic confirmation of non-muscle invasive bladder cancer of the transitional cell carcinoma high-grade subtype (mixed histology tumors allowed if transitional cell histology is predominant histology).
  - a. **Cohort A:** Histologically confirmed CIS (with or without Ta/T1 disease);  
**Cohort B:** Histologically confirmed high-grade papillary disease (Ta/T1 only).
  - b. 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 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.
  - c. 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  $\geq$  18 years.

4. **Performance status:** ECOG performance status of 0, 1, or 2.
5. BCG-naïve disease as defined as either of the following:
  - a. Have not received prior intravesical BCG; or
  - b. Previously received BCG, but stopped receiving more than 3 years before date of randomization.

**NOTE:** Additional criteria as defined in full study protocol. <https://clinicaltrials.gov/study/NCT02138734>

**EXCLUSION CRITERIA:** Patients with ANY of the following criteria are excluded from participation in the study:

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.

**NOTE:** Additional criteria as defined in full study protocol. <https://clinicaltrials.gov/study/NCT02138734>