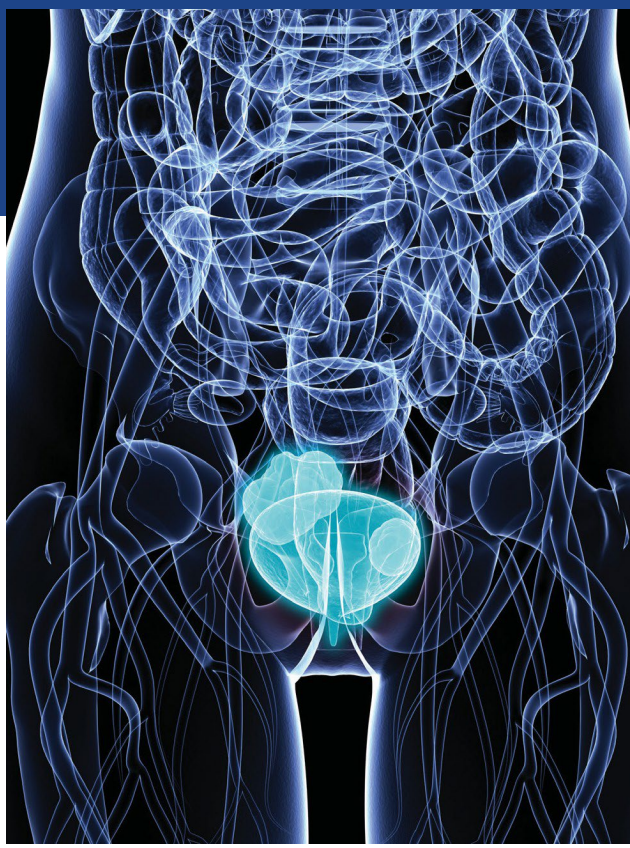
QUILT 2.005

NCT02138734

BCG-Naïve Non-Muscle Invasive Bladder Cancer (NMIBC)



A national study is enrolling participants recently diagnosed with non-muscle invasive bladder cancer (NMIBC) who have not received the standard of care treatment, Bacillus Calmette-Guerin (BCG), or have not received BCG in the last 3 years. In the phase 2b QUILT 2.005 trial, participants will receive either a combination of ImmunityBio's ANKTIVA® (which was recently approved by the FDA for BCG-unresponsive non-muscle invasive bladder cancer CIS with or without papillary tumors), plus BCG or BCG alone. This study aims to determine if the combination therapy is more effective in eliminating cancer than BCG alone.

Who May Be Eligible to Participate?

Individuals recently diagnosed with NMIBC who have not received prior BCG treatment for the disease or have not received BCG in the last 3 years.

STUDY TREATMENT	The study treatment includes a 6-week induction course, an optional re-induction course, and maintenance consisting of 3 consecutive weeks at 3, 6,12,18, 24, 30 and 36 months.

Study Objectives

- Assessment of elimination of the cancer, referred to as a 'complete response' 6 months after the initiation of treatment in patients with CIS disease.
- Assessment of the length of time after the initiation of study treatment that a participant survives without any signs or symptoms of disease, referred to as 'disease-free survival' in patients with high-grade papillary disease.

Who May Qualify for this Study:

- Male or female participants 18 years of age or older
- Individuals diagnosed with NMIBC that is considered carcinoma-in-situ (CIS) or high-grade papillary disease
- Must be able to walk, care for themselves, and attend study-site visits

Note: this is not a complete list of criteria for participation in this study.

About the Study:

This is an open-label, phase 2b, randomized study, meaning both the study doctor and the participant will know which treatment the participant is receiving. All participants treated in the study will receive BCG plus N-803 or BCG alone weekly for 6 consecutive weeks. Visit: **https://clinicaltrials.gov/study/NCT02138734**

SCAN ME

Purpose:

The purpose of this study is to determine if the combination of N-803 plus BCG shows a similar or perhaps greater ability to eliminate cancer than BCG alone.

Discuss with your doctor.

Bring this postcard to your next visit.

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

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

Contact ImmunityBio to learn more

at **844-696-5235** or visit **Immunitybio.com/join-a-trial**