



QUILT-2.005

NCT02138734

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

Bring this brochure 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 for this indication.

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

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.

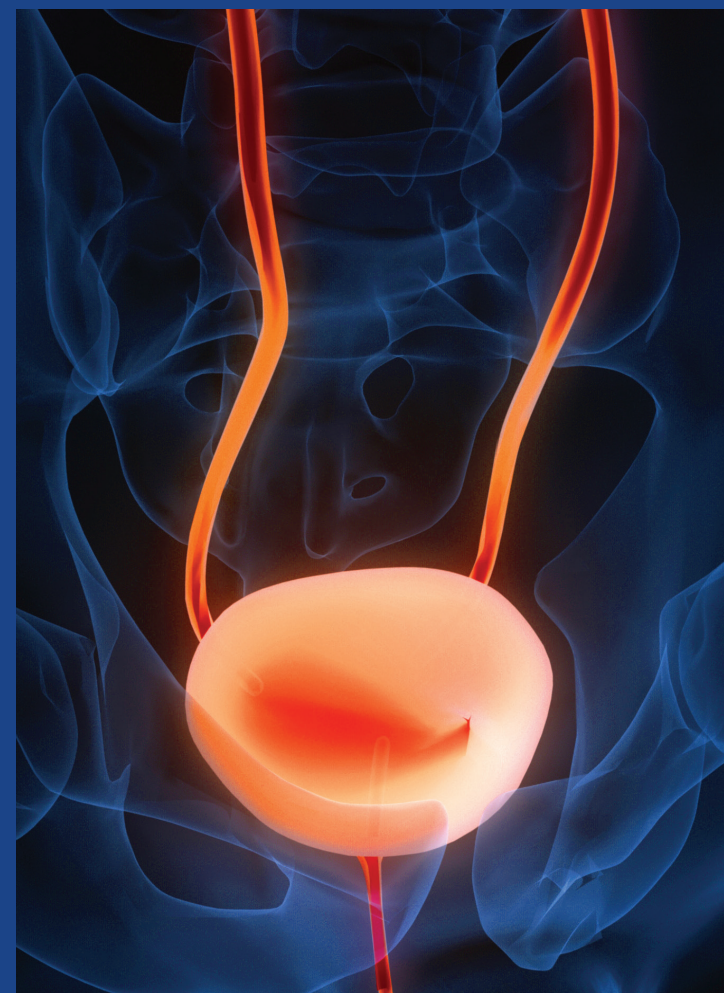
If you were recently diagnosed with NMIBC and have not received prior BCG treatment for the disease or have not received BCG in the last 3 years, you might qualify for our QUILT-2.005 clinical trial.

Discuss this with your doctor.

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



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



Purpose

ImmunityBio is studying N-803, an investigational drug, in clinical trials for different stages of non-muscle invasive bladder cancer (NMIBC).

QUILT-2.005 Clinical Trial

An international study is enrolling participants who have been recently diagnosed with non-muscle invasive bladder cancer (NMIBC) and have not yet received the standard treatment for NMIBC, Bacillus Calmette-Guérin (BCG), or have not received BCG in the last 3 years. In the phase 2b trial QUILT-2.005, sponsored by ImmunityBio, BCG naive participants with NMIBC will be randomized to receive either N-803 plus BCG or BCG alone. The study is designed to determine if the combination of N-803 and BCG shows a similar or improved clinical outcome and safety profile to your cancer than BCG alone.

Study Objectives

- **Carcinoma in Situ Cohort:** Assessment of elimination of the cancer, referred to as a 'complete response' within 6-months after the initiation of treatment.
- **Papillary Disease Cohort:** Assessment of the length of time after the initiation of study treatment that a participant survives without any signs or symptoms of disease.

Who May Qualify for this Study

- Individuals recently diagnosed with high-grade NMIBC who have not received prior BCG treatment for the disease or have not received BCG in the last 3 years
- Male or female participants 18 years of age or older
- Individuals diagnosed with NMIBC that is considered 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.

Study Treatment

Once approved for the study, you may receive BCG plus N-803 or BCG alone. The treatments will be administered by a tube (catheter) into your bladder once weekly for 6 consecutive weeks.

Following this period of treatment, you then may have ongoing maintenance treatments for 3 weeks in a row at 3, 6, 12, 18, 24, 30 and 36 months.

Participation Details

Will being in this research benefit me?

It is not known whether you will experience any personal benefit from this research. Participating in this study may provide information for treatment of other patients with cancer in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include treatment with the standard of care therapy for your cancer or no treatment at all.