

QUILT 3.032

NCT03022825

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

A national study is enrolling participants with non-muscle invasive bladder cancer (NMIBC) who have not responded to treatment with bacillus Calmette-Guerin (BCG unresponsive). These cases are typically treated today by surgical removal of the bladder. In the Phase 2/3 trial, participants receive a combination of an investigational immune system enhancing agent (N-803) made by ImmunityBio along with BCG to determine if the combination will eliminate the cancer and prevent the need for surgery.

Who May Be Eligible to Participate?

Individuals diagnosed with NMIBC who have not responded to treatment with BCG despite adequate treatment



TREATMENT

BCG plus N-803 will be delivered directly into the bladder through a tube inserted into the bladder weekly for six weeks.

Main Outcome Measurement

- Assessment of elimination of the cancer, referred to as a 'complete response' at any time on the study
- Assessment of how many participants are disease-free at 12 months since their first study treatment
- Assessment of how many participants are able to avoid a cystectomy (surgical removal of the bladder)

Who May Qualify for this Study:

- Male or female patients 18 years of age or older
- Individuals diagnosed with BCG-unresponsive carcinoma-in-situ (CIS) or BCG-unresponsive high-grade 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 a Phase 2/3 open-label study, meaning both the doctor and the participant will know which treatment the participant is receiving. All participants treated in the study will receive BCG plus N-803 weekly for 6 consecutive weeks

Visit: <https://clinicaltrials.gov/study/NCT03022825>

Purpose:

If you were diagnosed with non-muscle invasive bladder cancer and did not respond to BCG, consider learning more about QUILT 3.032

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 3.032 study

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