A PHASE 3, SINGLE-ARM STUDY OF CG0070 IN SUBJECTS WITH NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) UNRESPONSIVE TO BACILLUS CALMETTE-GUERIN (BCG)

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Background CG0070 is a serotype 5 adenovirus engineered to express GM-CSF and replicate in cells with mutated or deficient RB, with response rates (RR) of approximately 45% observed in patients with recurrent NMIBC after BCG. 1 2 This single arm phase 3 study (NCT04452591) was launched to confirm the clinical activity of CG0070 in patients with BCG Unresponsive NMIBC.

Methods 110 patients with BCG-unresponsive CIS with or without concurrent Ta or T1 disease will be treated with intravesical (IVe) CG0070 at a dose of 1x10e12 vp. CG0070 will be administered as follows: induction weekly x 6 followed by weekly x 3 maintenance instillations at months 3, 6, 9, 12, and 18. Patients with persistent CIS or HG Ta at 3 m may receive re-induction with weekly x 6 CG0070. Assessment of response will include q 3 m cystoscopy with biopsy of areas suspicious for disease, urine cytology, CTU/MRU, and mandatory bladder mapping at 12 m. Detection of high grade disease within the bladder will be enumerated as recurrence or non-response. The primary endpoint of the study is CR at any time on study as assessed by biopsy (directed to cystoscopic abnormalities and mandatory mapping at 12 m), urine cytology, and radiography, as above. Secondary endpoints include CR at 12 m, duration of response, progression free survival, cystectomy free survival and safety. Correlative assessments include changes in the tumor immune microenvironment, systemic immune induction as reflected in the peripheral blood and urine, as well as viral replication and transgene expression. Baseline expression of coxsackie adenovirus receptor, E2F transcription factor as well as anti-adenovirus antibody titer will be correlated with tumor response. Study enrollment globally is ongoing.

Trial Registration NCT04452591

REFERENCE

Ethics Approval CASTLE IRB: BOND-003 (CG3002S)

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