EG-70-101 (LEGEND)

A PIVOTAL PHASE 2 STUDY OF EG-70 IN PATIENTS WITH NON-MUSCLE INVASIVE BLADDER CANCER WITH CIS WHO ARE BACILLUS CALMETTE-GUÉRIN (BCG) UNRESPONSIVE AFTER ADEQUATE TREATMENT

Phase 2: Ongoing

Phase 1: Completed

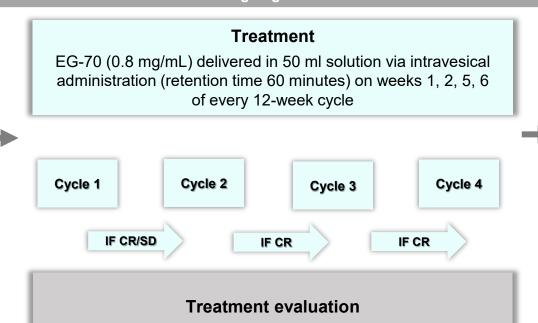
Cohort 1: BCG unresponsive

(N≈100)

- NMIBC with carcinoma in situ (CIS) with or without coexisting papillary (Ta/T1) tumors
- Persistent high-grade disease (Ta, T1, or TIS) or recurrence after 12 months of receiving ≥1 course of intravesical BCG (≥5 of 6 induction, and ≥2 maintenance or reinduction doses)

Key eligibility criteria

- Persons ≥18 years of age
- ECOG Performance Status 0, 1, 2
- Ineligible for, or electing not to undergo, cystectomy
- Adequate bladder function with ability to retain study drug for ≥ 60 minutes



Response will be assessed by cystoscopy, urine cytology, biopsy

- If CR or SD at end of Cycle 1, continue with Cycle 2
- After Cycle 2, only patients with a CR will continue for up to 2 more cycles, discontinuation will occur at SD or PD

Post-treatment follow-up

Follow for 2 additional years:

- Duration of Response
- Subsequent Treatment/Cystectomy

Objectives

- **Primary:** Efficacy (CR at 48 weeks), Safety
- Secondary: DFS, CR at end of each cycle, duration of CR
- Exploratory: ADA, PK, Biomarkers

LEGEND
ClinicalTrials.gov
NCT04752722