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 1: Completed

Phase 2: Ongoing

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

Treatment

EG-70 (0.8 mg/mL) delivered in 50 ml solution via intravesical administration (retention time 60 minutes) on weeks 1, 2, 5, 6 of every 12-week cycle

Cycle 1 → **Cycle 2** → **Cycle 3** → **Cycle 4**

IF CR/SD → IF CR → IF CR

Treatment evaluation

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

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ClinicalTrials.gov
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ADA, anti-drug antibodies; BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CR, complete response; W, week; DFS, disease-free survival; NMIBC, non-muscle invasive bladder cancer; PD, progressive disease; PK, pharmacokinetics; SD, stable disease; TURBT, transurethral resection of bladder tumor; ECOG, Eastern Cooperative Oncology Group