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**Protocol Title: A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 in Patients With Non-Muscle Invasive Bladder Cancer**

### Key Inclusion criteria

1. Histologic confirmation of non-muscle invasive bladder cancer of the transitional cell carcinoma high-grade subtype (mixed histology tumors allowed if transitional cell histology is predominant histology).
  - a. Cohort A: Histologically confirmed CIS (with or without Ta/T1 disease)
  - b. Patients are eligible if the diagnostic biopsy was done within 3 months of treatment start and a cystoscopy demonstrating no resectable disease was done within 6 calendar weeks (inclusive of 48 days) of treatment start (residual CIS is acceptable; patients with T1 disease must undergo repeat resection if muscularis propria is not present in each biopsy sample). Patients with high-grade Ta and/or T1 disease should have complete resection before study treatment.
  - c. Upper tract imaging within 6 months prior to study entry must not be suspicious for upper tract malignancy.
2. Currently eligible for intravesical BCG therapy.
3. Age  $\geq$  18 years.
4. Performance status: ECOG performance status of 0, 1, or 2
5. BCG-naive disease as defined as either of the following:
  - a. Have not received prior intravesical BCG; or
  - b. Previously received BCG but stopped receiving more than 3 years before date of randomization.

**For more information please contact**

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