Protocol Title: Phase III Randomized Trial to Evaluate the Influence of BCG Strain Differences and T Cell Priming with Intradermal BCG Before Intravesical Therapy for BCG-Naive High-Grade Non-Muscle Invasive Bladder Cancer (S1602)

Target Population: Stage 0, 0is, or I Bladder Urothelial Carcinoma

Summary: To compare whether time to high grade recurrence (TTHGR) for patients with BCG-naïve, Non-Muscle Invasive Bladder Cancer (NMIBC) receiving Tokyo-172 BCG Strain (Arm II) is non-inferior to patients receiving TICE BCG Strain (Arm I). To test whether TTHGR for patients with BCG-naïve, NMIBC receiving intradermal Tokyo-172 BCG Vaccination followed by intravesical Tokyo-172 BCG instillation (Arm III) is superior to patients receiving intravesical Tokyo-172 BCG instillation without prior intradermal BCG Vaccination (Arm II).

Key Inclusion Criteria:
- Patients must have histologically proven Ta, Carcinoma in Situ (CIS) or T1 Stage Urothelial Cell Carcinoma of the Bladder within 90 Days of registration.
- Patients must have had all grossly visible Papillary Tumors removed within 30 Days prior to registration or Cystoscopy confirming no grossly visible Papillary Tumors within 30 Days prior to registration.
- Patients with T1 disease must have cross-sectional imaging of Abdomen / Pelvis demonstrating no evidence of metastatic disease (MRI or CT Scan) within 90 Days prior to registration.
  - T1 disease must have re-resection confirming ≤ T1 disease within 90 Days prior to registration.
- Patients must have High-Grade Bladder Cancer.
- Patients must NOT have pure Squamous Cell Carcinoma or Adenocarcinoma.
- Patients' disease must not have micropapillary components.
- Patients must have no evidence of Upper Tract (Renal Pelvis or Ureters) Cancer confirmed by one of the following tests performed within 90 Days prior to registration:
  - CT Urogram
  - Intravenous Pyelogram
  - MR Urogram
  - Retrograde Pyelograms
- Patients must not have nodal involvement or metastatic disease.
- Patients must not have received prior intravesical BCG.
- Patients must not have known history of Tuberculosis.
- Patients must be PPD negative within 90 Days prior to registration.
- Patients must not be taking oral glucocorticoids at the time of registration.
- Patients must not be planning to receive concomitant biologic therapy, hormonal therapy, chemotherapy, surgery, or other cancer therapy while on study.

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For additional information: https://clinicaltrials.gov/ct2/show/study/NCT03091660