EA8212/BRIDGE

For Patients with Bladder Cancer

EA8212 Available Through ECOG-ACRIN Cancer Research Group

A Randomized Phase III Trial of Intravesical BCG veRsus Intravesical Docetaxel and GEmcitabine Treatment in BCG High Grade Non-Muscle Invasive Bladder Cancer (BRIDGE)

Patient Population
See Section 3 for Complete Eligibility Details

- Age ≥ 18 years, ECOG PS 0-2, adequate lab values
- Must not have any prior or current history of muscle-invasive (i.e., T2, T3, T4), locally advanced unresectable, or metastatic urothelial carcinoma as assessed on radiographic imaging (CT or MRI of the abdomen/pelvis) obtained within 90 days of randomization
- Must have histologically confirmed high-grade non-muscle invasive urothelial carcinoma of the bladder (HGTa, HGT1, CIS, HGTa + CIS, or HGT1 + CIS stage) on TURBT obtained within 90 days of randomization
- Must have all visible papillary tumor resected by the treating urologist at the site registering the patient (if the treating urologist did not perform the TURBT, he/she must perform a cystoscopy within 28 days of randomization)
- Must not have prostatic involvement
- Must not have received prior intravesical therapy for bladder cancer (exception: perioperative chemo at the time of TURBT)
- Patients with high grade T1 disease must have undergone a restaging TURBT within 90 days of Step 1 randomization
- Must not have pure squamous cell carcinoma or adenocarcinoma; must not have any component of neuroendocrine carcinoma
- Must not have any component of sarcomatoid, micro-papillary, or plasmacytoid variant histology
- May have received prior systemic gemcitabine/docetaxel if it was for a non-bladder malignancy
- No history of severe hypersensitivity reactions to docetaxel or drugs formulated with polysorbate 80
- HIV, HBV, HCV patients are permitted per protocol
- Patients with known history or current symptoms of cardiac disease or history of treatment with cardiotoxic agents should be NYHA class 2b or better

Treatment Plan
See Section 5 for Complete Treatment Details

Arm A– Gemcitabine + Docetaxel (Induction followed by Maintenance):
- GEMDOCE is given intravesically (per protocol) once a week (+/- 3 days) for 6 consecutive weeks
- Maintenance: Patients with a CR or resected low grade noninvasive bladder cancer (LgTa) after induction (i.e., at the 3 month cystoscopic evaluation) will begin monthly GEMDOCE instillations (+/- 5 days each month) per protocol for up to 2 years, with cystoscopic and cytologic evaluations every 3 months while on treatment

Arm B– BCG (Induction then Maintenance):
- BCG 50 mg in 50mL 0.9% NaCl is given intravesically (per protocol) once a week (+/- 3 days) for 6 consecutive weeks
- NOTE: A maximum of 9 weeks is allowed for completion of intravesical BCG induction
- Maintenance: Patients with a CR or resected low grade noninvasive bladder cancer (LgTa) after induction (i.e., at the 3 month cystoscopic evaluation) will begin BCG maintenance instillations per protocol once a week for 3 consecutive weeks at months 3, 6, 12, 18, 24, 30, and 36 (total of 21 maintenance instillations); cystoscopic and cytologic evaluations every 3 months while on treatment

Notes:
- A max of 6 weeks is allowed for the completion of each monthly instillation during intravesical GEMDOCE maintenance; or each set of 3 weekly instillations during BCG maintenance
- Patients with either persistent CIS or completely resected HGTa at the 3 month surveillance may undergo reinduction per protocol
- See protocol Section 5.2 for surveillance (cystoscopy, cytology, and biopsy schedule/details)
- Treatments may be administered at an outside institution (see protocol for details)

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org/open

Protocol Information

Please Enroll Your Eligible Patients!