

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 **GE**mcitabine Treatment in BCG High Grade Non-Muscle Invasive Bladder Cancer (**BRIDGE**)

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age \geq 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 urethral 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, micropapillary, 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 5.0 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 followed by Maintenance):

- BCG 50 mg in 50mL 0.9% NaCl is given intravesically (per protocol) once a week for 6 consecutive weeks
 - ◇ *NOTE: A maximum of 9 weeks is allowed for completion of intravesical BCG induction*
- **Maintenance:** Patients with a CR or 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>

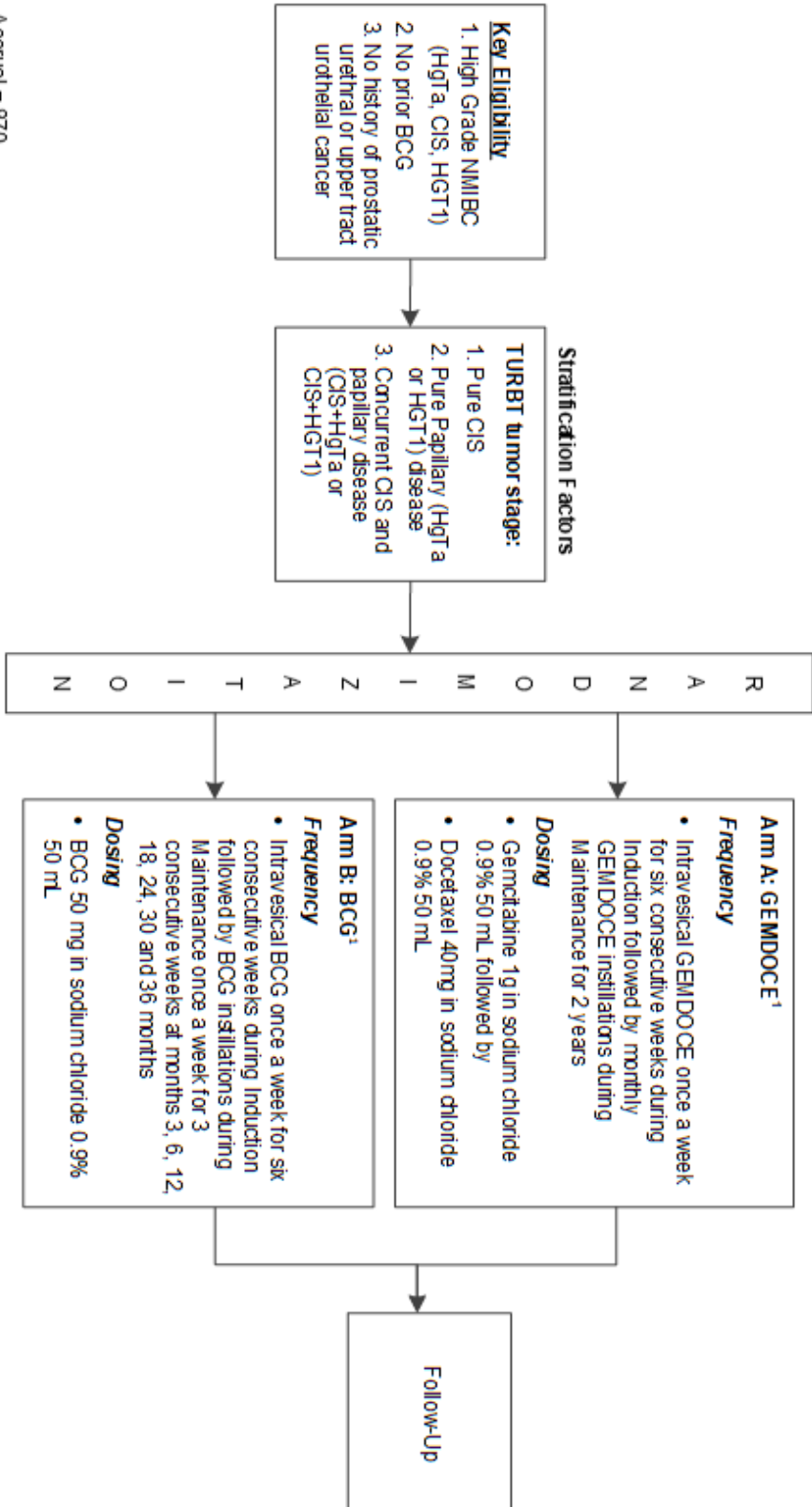
Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, <http://ecog-acrin.org> (Member Login)

Please Enroll Your Eligible Patients!

EA8212

Schema



Accrual = 870

1. Please refer to Section 5.1 for detailed instructions on Arm A and B intravesical therapy procedures.