Clinical Trial Reference Guide

Active and planned trials as of April 2025

Non-Muscle Invasive Bladder Cancer (NMIBC)

Intermediate-Risk[1]

- Low-Grade (LG) Ta:
  - Multifocal OR
  - solitary >3 cm OR
  - Recurrent in <12 months
- LG T1
- HG Ta: Solitary AND primary AND ≤3cm

PIVOT-006

High-Risk[1]

- High-Grade (HG) T1
- HG Ta: Multifocal OR recurrent OR >3cm
- CIS
- BCG failure in HG patient

BCG-Naïve[2]

- No BCG ever/ within 24 months
- Only 1-2 BCG doses within 24 months

CIS or Papillary-only disease

CORE-008 COHORT A

BCG-Exposed

- HG Ta or CIS after induction BCG (min. 5 doses)
- HG recurrence within 24 months of BCG (excluding BCG-unresponsive patients)

CIS or Papillary-only disease

CORE-008 COHORT B

- HG Ta or CIS after induction BCG (min. 5 doses)
- HG recurrence within 24 months of BCG (excluding BCG-unresponsive patients)

CIS +/- Ta/T1

CORE-008 COHORT CX

BCG-Unresponsive[3]

- HG Ta or CIS after induction and maintenance BCG (min 5+2 doses)
- Relapse of HGTa/T1 within 6 months or CIS within 15 months of BCG (min. 5+2 doses)

with CIS

CRETO-EAP
EXPANDED ACCESS PROGRAM

- HG T1 after induction BCG (min. 5 doses)
- HG Ta or CIS after induction and maintenance BCG (min 5+2 doses)
- Relapse of HGTa/T1 within 6 months or CIS within 12 months of BCG (min. 5+2 doses)

Papillary-only disease

BOND-003 COHORT P

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Attacking Bladder Cancer for a Better Tomorrow™

PIVOT-006

Cretostimogene Monotherapy in Intermediate-Risk NMIBC

NCT06111235

CORE-008 COHORT A

Cretostimogene Monotherapy in BCG-Naïve, High-Risk NMIBC

CIS or papillary only disease

NCT06567743

CORE-008 COHORT B

Cretostimogene Monotherapy in BCG-Exposed, High-Risk NMIBC

CIS or Papillary-only disease

NCT06567743

CORE-008 COHORT CX

Cretostimogene and gemcitabine combination therapy in BCG-exposed or BCG unresponsibe, High-Risk NMIBC

CIS +/- Ta/T1

NCT06567743

CRETO-EAP EXPANDED ACCESS PROGRAM

Cretostimogene Monotherapy in BCG-Unresponsive, High-Risk NMIBC

with CIS*

NCT06443944

BOND-003 COHORT P

Cretostimogene Monotherapy in BCG-Unresponsive, High-Risk NMIBC

Papillary-only disease

NCT04452591

Important Inclusion/Exclusion Criteria:**

- Must be ≥18 years of age & ECOG 0-2 (0-3 for EAP)
- Must have adequate organ function
- Complete resection of papillary tumors prior to cretostimogene treatment initiation
- No muscle-invasive bladder carcinoma history
- No significant immunodeficiency, active infection, active hepatitis or recent major cardiovascular or surgical events
- For patients with a history of other malignancies, upper tract or prostatic urethral carcinoma, refer to specific protocol

Reference: 1. Holzbeierlein J, Bixler BR, Buckley DI, et al. Diagnosis and treatment of non-muscle invasive bladder cancer: AUA/SUO guideline: 2024 amendment. *J Urol*. 2024;10.1097/JU.0000000000003846. **2.** International Bladder Cancer Group Consensus Statement on ClinicalTrial Design for Patients with Bacillus Calmette-Guérin–exposed High-risk Non–muscle-invasive Bladder Cancer https://pubmed.ncbi.nlm.nih.gov/34955291/ **3.** FDA Guidance Document: BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment. February 2018

* This trial is for patients who are not eligible for our clinical trials and may not have options for alternative therapies. Please see clinical studies page on CGOncology.com for more information.

**see specific trial protocol for numerical & time-bound limits & additional criteria

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