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PIVOT-006: A Phase 3, Randomized Study of Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk NMIBC Following TURBT

TPS715

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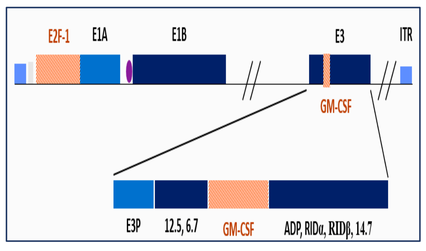
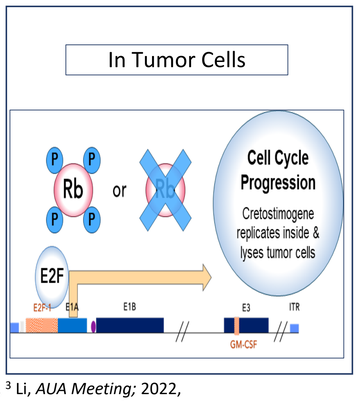
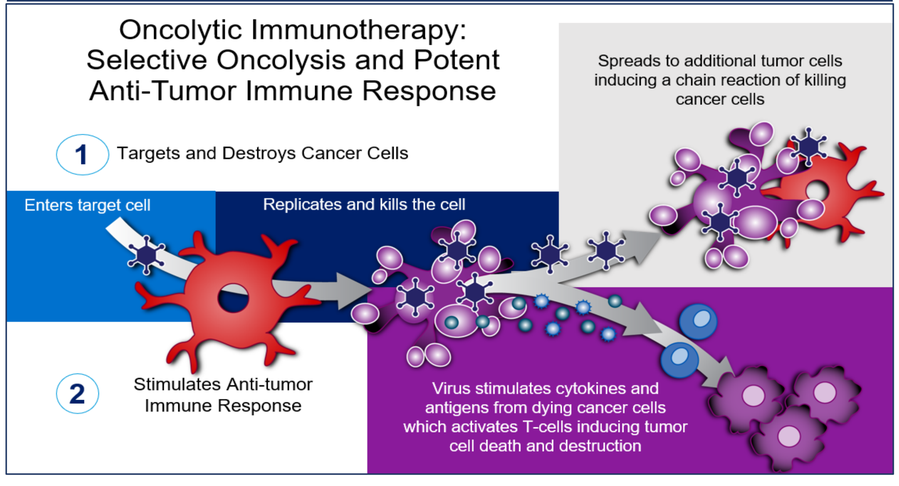
BACKGROUND

- Cretostimogene is a conditionally replicating, intravesically delivered adenovirus
- Oncolytic immunotherapy: Cretostimogene is engineered to selectively replicate and lyse Rb-altered bladder cancer cells and produce GM-CSF, stimulating the immune system via a dual mode of action
- In High Risk NMIBC, cretostimogene shows Complete Response rates between 46-85% [1-4]
- In Intermediate Risk NMIBC, Guidelines recommend intravesical therapy or observation, yet recurrence rates are high, 30-60% [5,6]





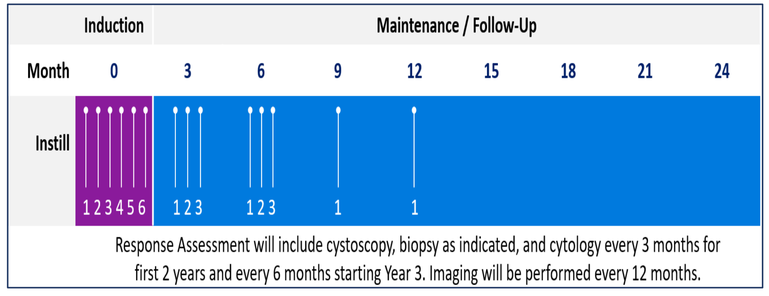
SUO-CTC Sponsored Trial in Progress at over 90 North American Sites



STUDY DESIGN

- Eligible participants with Intermediate Risk NMIBC by American Urologic Association Risk Criteria
- ECOG 0-2, Randomized 1:1, up to 426 patients. Option for crossover to treatment, if recurrence in Observation arm.
- Stratified by perioperative chemotherapy and tumor grade; 1° endpoint Recurrence Free Survival
- Robust patient reported outcomes and biomarkers

Study Administration Schedule



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References: [1] Burke, *J Uro*; 2012, [2] Packiam, *Uro Onc;* 2018, [3] Li, *AUA Meeting;* 2022, [4] Tyson, *SUO Meeting;* 2023, [5] NCCN Bladder Cancer Guidelines; 2023, [6] Messing, *JAMA;* 2018

ASCO® Genitourinary Cancers Symposium

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Abstract TPS715

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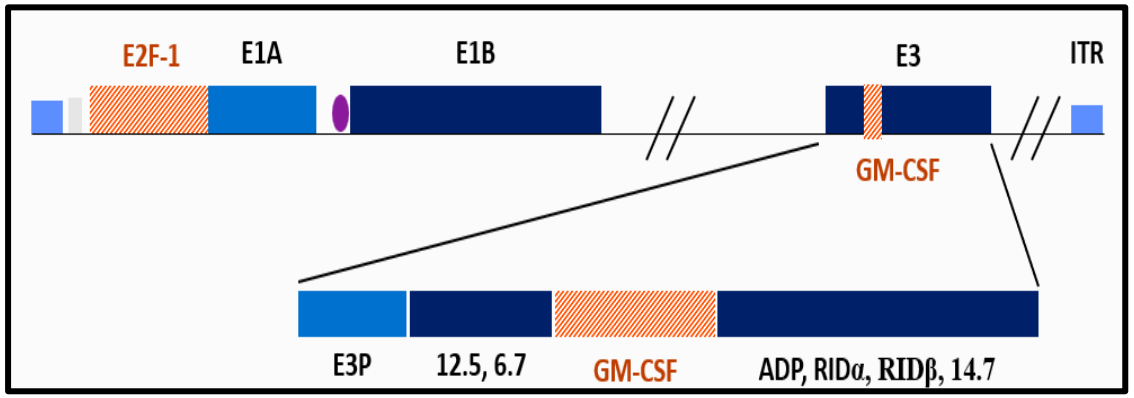
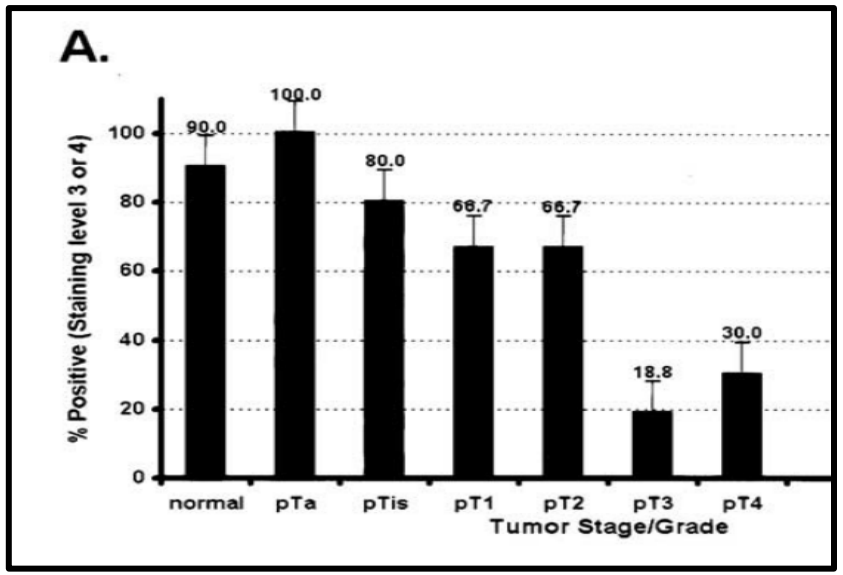
UT Health San Antonio, TX

What is Cretostimogene Grenadenorepvec?

- Conditionally replicating adenovirus
  - Highly immunogenic
  - Encodes GM-CSF
  - Insertion of human E2F-1 promoter
- Binds to Coxsackie Adenovirus Receptor (CAR)
  - Robust expression in all stages of bladder cancer
- Viral replication results in tumor lysis in Rb-altered cells
  - Oncolytic immunotherapy, dual mode of action

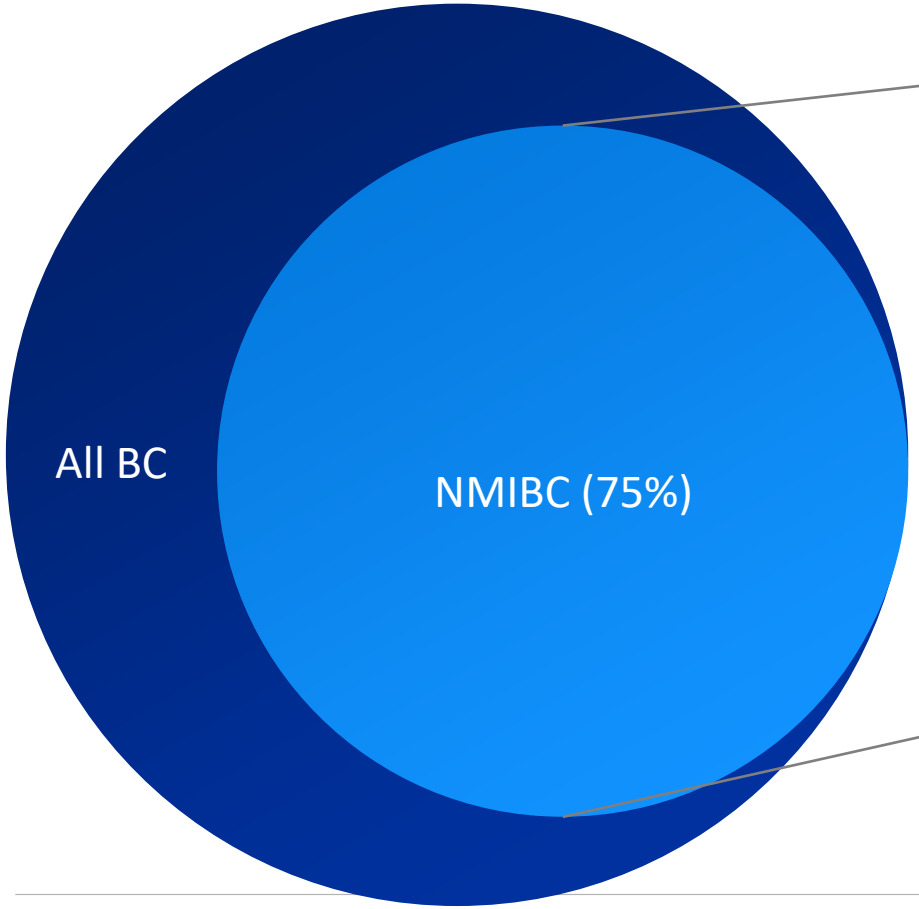




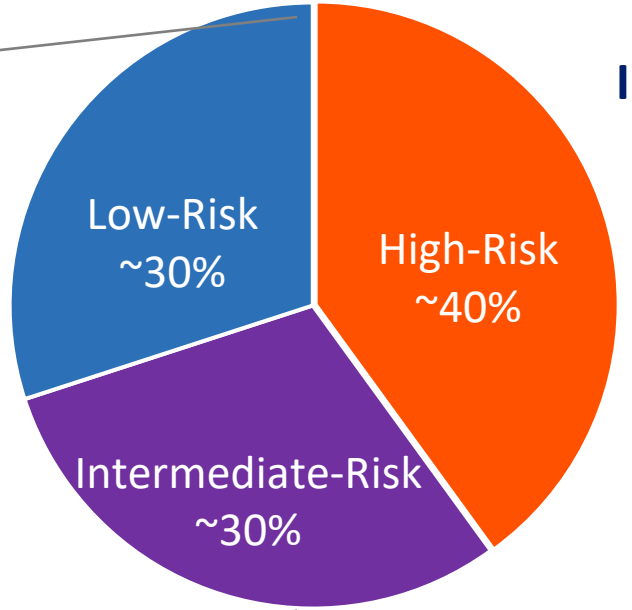
CG Oncology proprietary illustration.
Sachs, et al. *Urology;* 2002

Significant Unmet Need with High Prevalence of Intermediate-Risk NMIBC in the U.S.

NMIBC Prevalence in U.S. [1]



NMIBC Risk Stratification



Intermediate Risk NMIBC

- **High Recurrence; 50-70%**[2]
- **Low Progression; < 5%** [2]
- **Common**[2]
- **Costly**[3]
- **Chronic**[4]
- **Risk of Anesthesia, Surgery**[5]

[1] SEER Cancer Stat Facts: Bladder Cancer
[2] Babjuk, et al. *Eur Uro;* 2019
[3] Mossanen, et al. *World J Urol;* 2019
[4] Sharma, et al. *J Uro;* 2021, Suppl 3
[5] Erikson, et al. *Scand J Uro;* 2020

PRESENTED BY: Robert S. Svatek, MD, MSCI

NCCN Guidelines Version 2.2023
Non-Muscle Invasive Bladder Cancer

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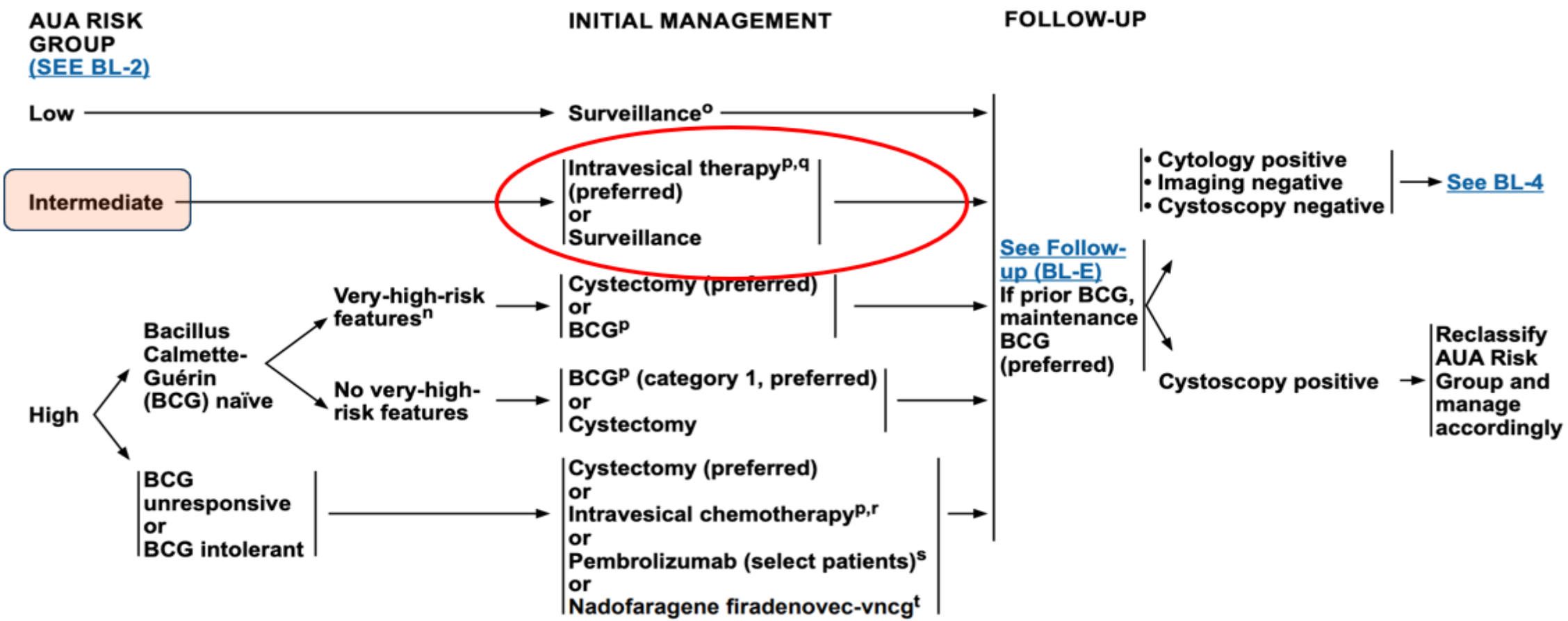
MANAGEMENT PER NMIBC RISK GROUP



PIVOT-006

Phase 3 Adjuvant Cretostimogene vs TURBT Alone for IR-NMIBC

N = Up to 426

Design: Two arms, IVe cretostimogene after TURBT vs TURBT

Trial Type: Open label

Regimen:
Cretostimogene Induction and Maintenance

Endpoints: RFS, RFS at 12-month and 24-month, PFS, & Safety

Exploratory: Biomarkers and PROs

Key Entry Criteria

- IR-NMIBC
  - Solitary LG Ta >3cm
  - Multifocal LG Ta
  - LG T1
  - LG Recurrent ≤ 1 yr
  - HG Ta ≤ 3cm
- Adequate organ function
- ECOG 0-2

1:1 Randomization

Stratification:
Perioperative Chemo, HG vs LG

Geography:
North America

Arm A: Cretostimogene After Complete TURBT

Disease Assessments in Each Arm:
Every 3 mos cystoscopy, urine cytology, for 2 years; then every 6 months starting Year 3

Arm B: Complete TURBT Alone

Arm B patients offered Cretostimogene treatment following IR-NMIBC recurrence

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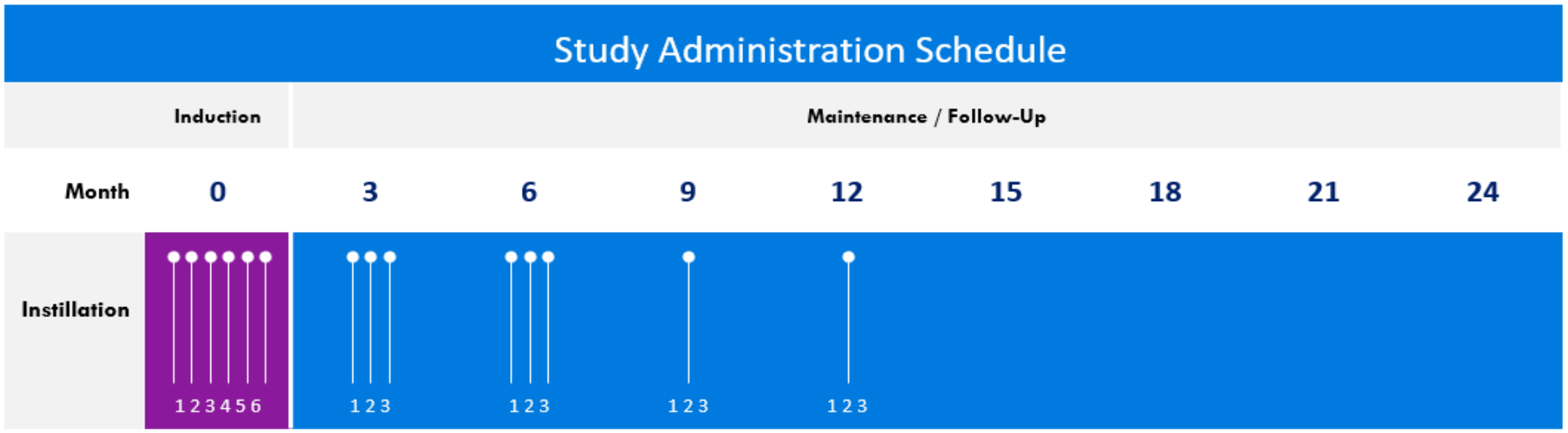

Response Assessment will include cystoscopy, biopsy as indicated, and cytology every 3 months for first 2 years and every 6 months starting Year 3. Imaging will be performed every 12 months.

SUO-CTC and BCAN Support- PIVOT-006
Over 90 North American Sites

PIVOT-006

SUO CTC
Society of Urologic Oncology Clinical Trials Consortium, Inc.

BCAN
Bladder Cancer Advocacy Network
Leading the way to awareness and a cure