

Trial in Progress: PIVOT-006 – A Phase 3, Randomized Study of Adjuvant Intravesical Cretostimogene Grenadenorepvec Versus Surveillance for the Treatment of Intermediate-Risk Non-Muscle Invasive Bladder Cancer



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BACKGROUND

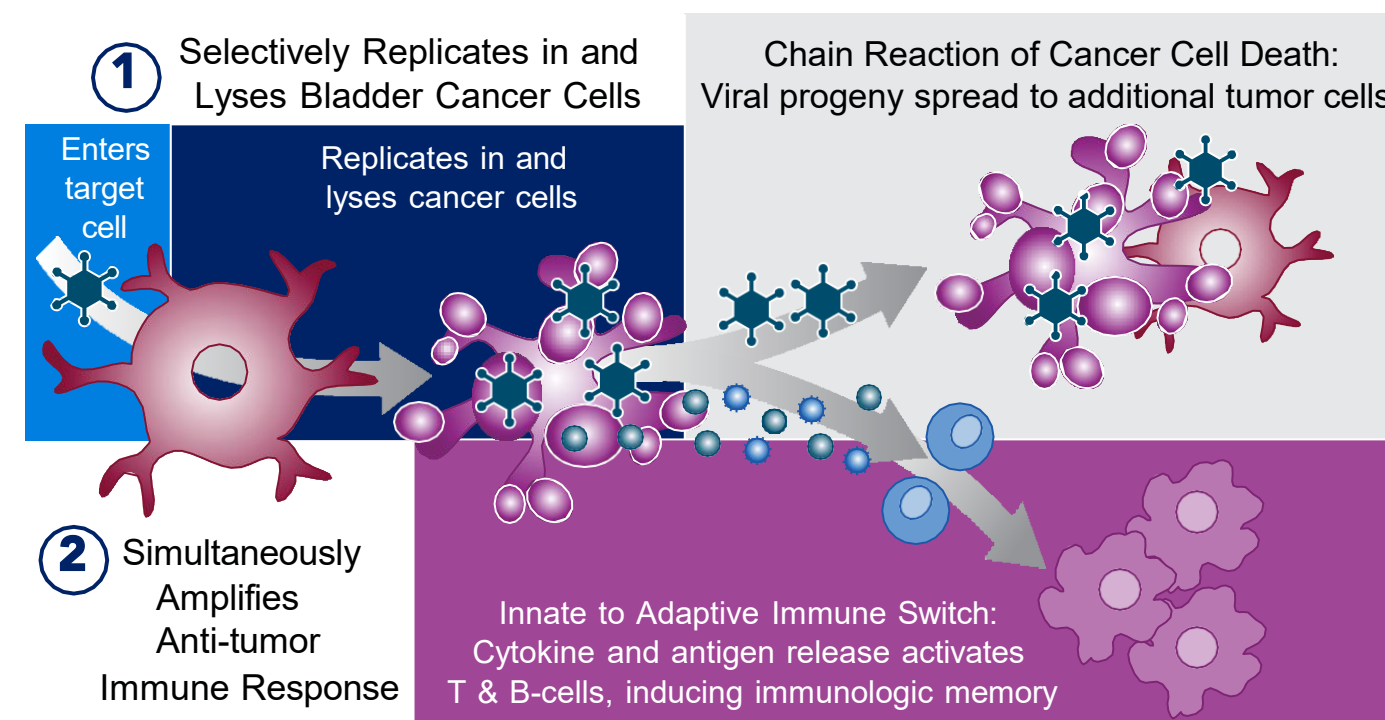
- IR-NMIBC patients represent 30% of NMIBC population ¹
- In Intermediate-Risk NMIBC, guidelines recommend intravesical therapy or surveillance, yet recurrence rates remain high at 30-60% ²⁻³
- With real-world data suggesting lack of adjuvant chemotherapy use, surveillance is the most appropriate real-world comparator ⁴
- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action: it selectively replicates in and lyses cancer cells while amplifying the immune response against bladder tumors
- Granted US FDA Fast Track and Breakthrough Therapy Designations in HR BCG-UR NMIBC CIS +/- Ta/T1

PIVOT-006 is a multi-center, randomized Phase 3 study to assess the efficacy and safety of adjuvant cretostimogene versus surveillance in patients with IR NMIBC

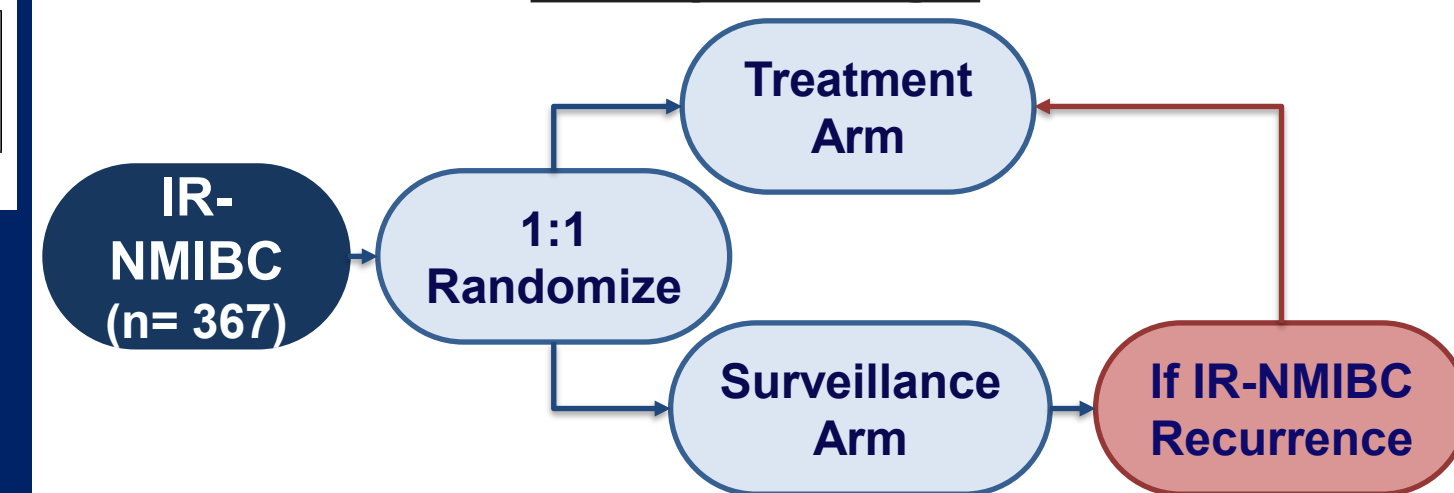


Adjuvant IR-NMIBC Randomized Controlled Trial Enrollment Completed 90+ North American Sites

Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action



Study Design



- Intermediate-Risk eligibility per AUA/SUO guidelines
- Patients may be offered cretostimogene treatment, if Intermediate-Risk recurrence in surveillance arm
- Primary endpoint is Recurrence-Free Survival
- Stratification by perioperative chemotherapy & tumor grade
- Robust patient reported outcomes and biomarkers
- Response assessments include cystoscopy, biopsy as indicated & cytology every 3 months for first 2 years and every 6 months starting Year 3

Study Administration Schedule

	Induction						Maintenance/Follow-Up					
	Month	0	3	6	9	12	15	18	21	24		
Instillation		●●●●●● 1 2 3 4 5 6	●●● 1 2 3	●●● 1 2 3	● 1	● 1						

Abbreviations: BCG = Bacillus Calmette-Guerin; IR = intermediate-risk; NMIBC = non-muscle invasive bladder cancer

References: 1 SEER; 2019, 2 NCCN Bladder Cancer Guidelines; 2025 3 AUA/SUO NMIBC Guidelines; 2024, 4 Mori, *Urol Oncol*; 2020

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