

# PIVOT-006: Ongoing 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 <sup>1</sup>
- In Intermediate-Risk NMIBC, guidelines recommend intravesical therapy or surveillance, yet recurrence rates remain high at 30-60% <sup>2-3</sup>
- With real-world data suggesting lack of adjuvant chemotherapy use, surveillance is most appropriate real-world comparator <sup>4</sup>
- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action: it 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**

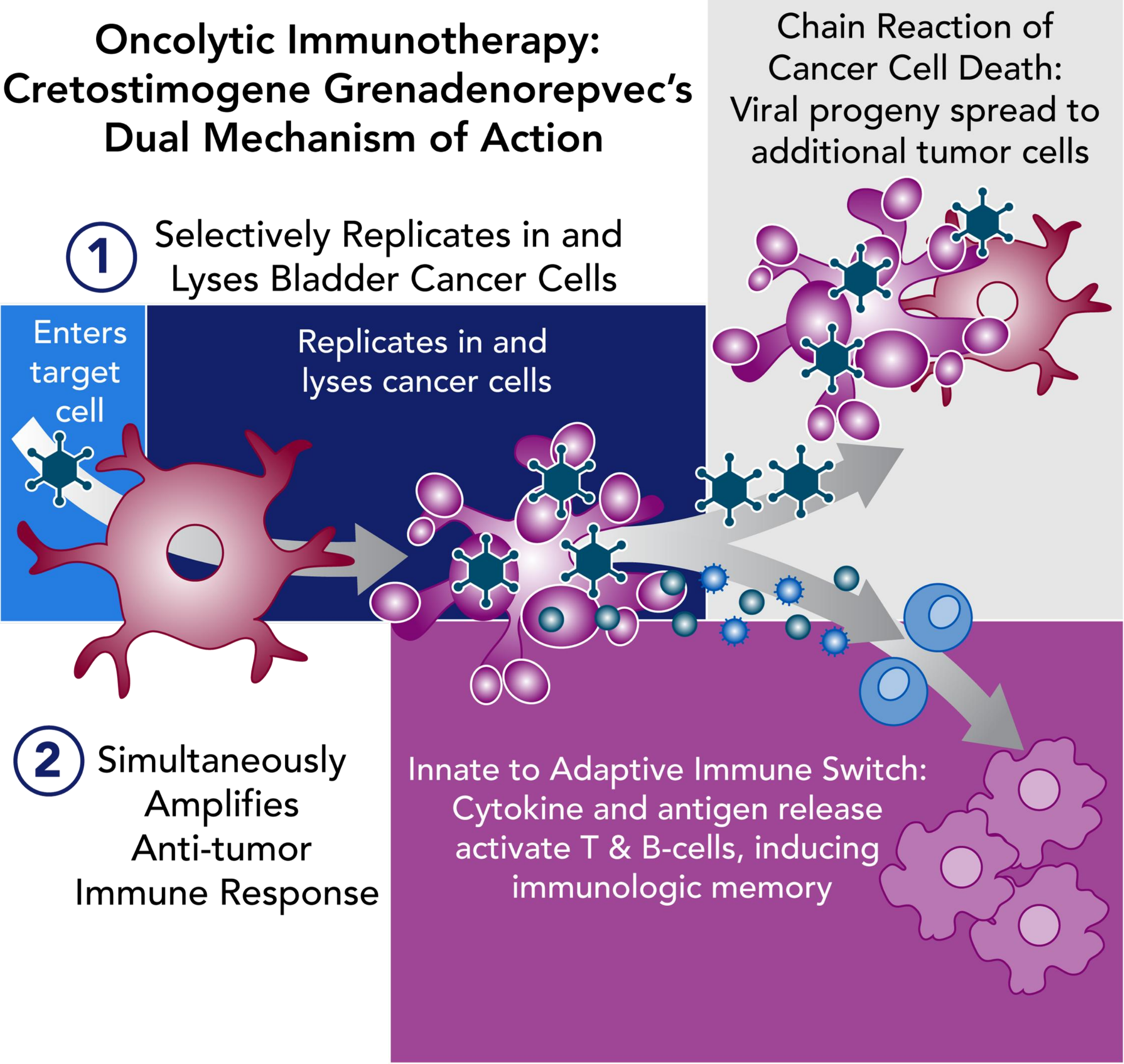
**Abbreviations:** BCG = Bacillus Calmette-Guerin; IR = intermediate-risk; NMIBC = non-muscle invasive bladder cancer

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

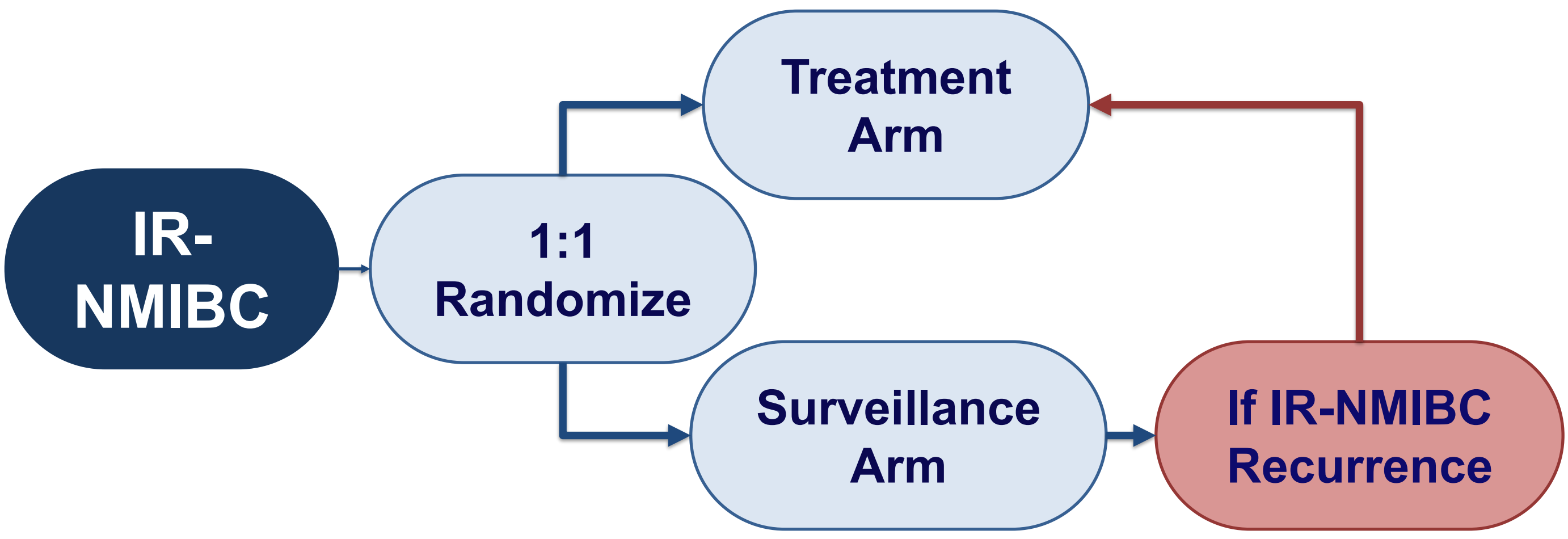
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### Adjuvant IR-NMIBC Randomized Controlled Trial

**Enrollment Complete**  
**90+ North American Sites**



## STUDY DESIGN



- Intermediate-Risk eligibility per AUA/SUO guidelines
- Recurrence in surveillance arm with option for cretostimogene treatment
- 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				