

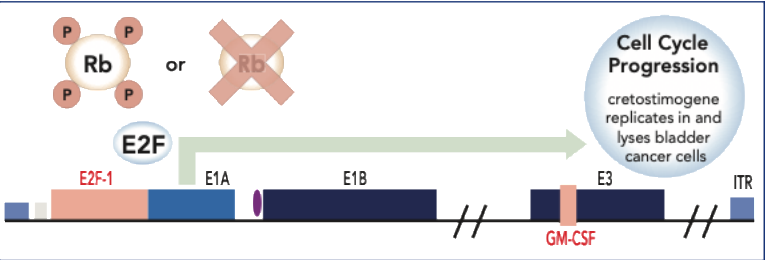
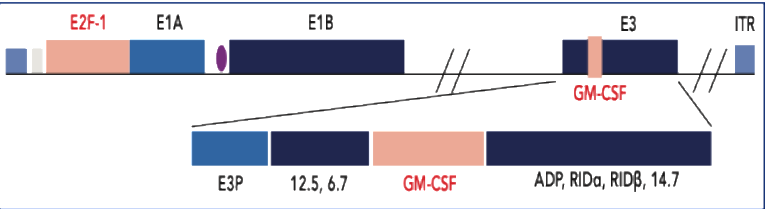
PIVOT-006: A Phase-3, Randomized Study of Cretostimogene Grenadenorepvec Versus Surveillance for the Treatment of Intermediate-Risk NMIBC

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BACKGROUND

- Cretostimogene grenadenorepvec is an oncolytic immunotherapy with a dual mechanism of action
- Selectively replicates in and lyses cancer cells while simultaneously amplifying the immune response against bladder tumors
- Cretostimogene demonstrates Complete Response rates of 46-85% with favorable safety and tolerability in High-Risk NMIBC previously treated with BCG ¹⁻⁵
- In Intermediate-Risk NMIBC, guidelines recommend intravesical therapy or surveillance, yet recurrence rates remain high at 30-60% ^{6,7}



References: 1 Burke, *J Urol*; 2012, 2 Packiam, *Uro Onc*; 2018, 3 Li, AUA Meeting; 2022, 4 Tyson, SUO Meeting; 2023, 5 Tyson, AUA Meeting, 2024; 6 NCCN Bladder Cancer Guidelines; 2024, 7 Messing, *JAMA*; 2018

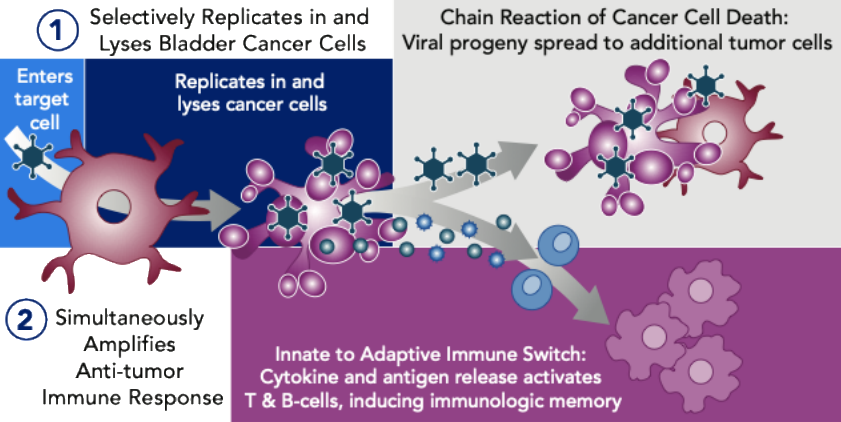
PIVOT-006

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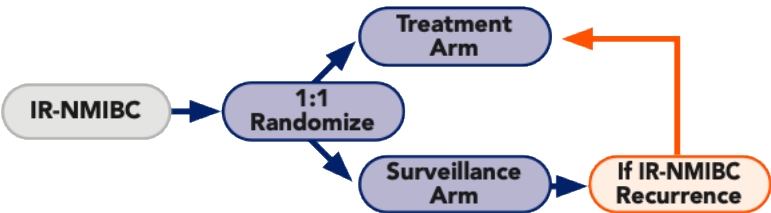
Trial in Progress

90+ North American Sites

Oncolytic Immunotherapy: Cretostimogene Grenadenorepvec's Dual Mechanism of Action



STUDY DESIGN



- Intermediate-Risk eligibility per AUA guidelines
- Recurrence in surveillance arm with option for cretostimogene treatment
- Primary endpoint Recurrence-Free Survival
- Stratification by perioperative chemotherapy & tumor grade
- Robust patient reported outcomes and biomarkers

Study Administration Schedule

	Induction			Maintenance/Follow-Up						
Month	0	3	6	9	12	15	18	21	24	
Instillation	<div><div></div><div></div><div></div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div></div>	<div><div></div><div></div><div></div></div>	<div><div></div></div>	<div><div></div></div>					
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Response Assessments include cystoscopy, biopsy as indicated & cytology every 3 months for first 2 years and every 6 months starting Year 3

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