Attacking Bladder Cancer for a Better Tomorrow™

Cretostimogene grenadenorepvec

PIVOT-006, Phase 3 Randomized Clinical Trial for Treatment of Intermediate-Risk NMIBC

PIVOT-006

PHASE 3 Clinical Trial

NOW ENROLLING

Who May Be Eligible to Take Part In This Study	Treatment	Main measure
People with: • Bladder Cancer that has not invaded the muscle (Non-Muscle Invasive Bladder Cancer) • Intermediate-Risk Disease • Over 18	All patients will receive surgical treatment on study as part of Standard-of-Care. 50% of patients will receive cretostimogene in addition to surgical treatment. For patients who do not receive cretostimogene, you will be offered cretostimogene if your bladder cancer recurs. The treatment will be instilled into the bladder through a thin tube called a catheter. This will be done 14 times over an 12-month period.	Patients who have recurrence of bladder cancer after receiving surgery plus cretostimogene compared to patients who receive surgery alone.

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BCAN
Bladder Cancer Advocacy Network

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

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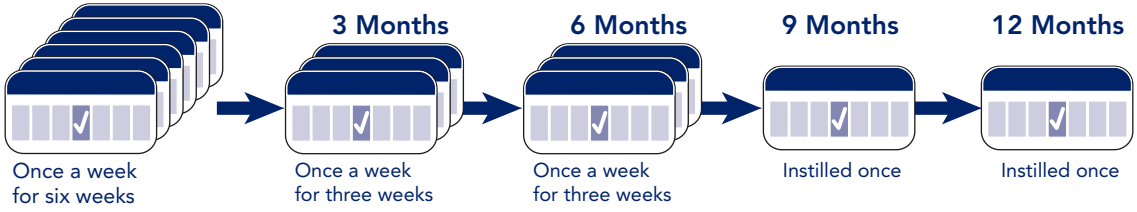
About the PIVOT-006 Phase 3 Randomized Trial:

Participants in the PIVOT-006 study will either receive surgical treatment plus cretostimogene or surgical treatment alone. The study is an open-label study, meaning both the doctor and the patient can know if they are receiving cretostimogene. Cretostimogene will be instilled into the bladder for a total of 14 times over a 12-month period.

If you are interested in learning more about the study:

- Contact recruitment@cgoncology.com
- Discuss with your urologist – bring this information with you.
- Visit https://clinicaltrials.gov/study/NCT06111235

PIVOT-006 Patient Instillation Pattern



What is the purpose of the study:

The purpose of this study is to see if cretostimogene can reduce the risk of your bladder cancer returning, or coming back as quickly as if you did not receive cretostimogene. People in the study will continue to be monitored by cystoscopy and pathology to see how long it takes for the cancer to return.

Cretostimogene is an experimental drug and not all risks are known. It is being studied to determine whether it is effective and safe in the treatment of Non-Muscle Invasive Bladder Cancer.

How does the treatment work?

We believe that cretostimogene goes into bladder cancer cells, kills them and also activates the immune system to work better to kill the cancer cells.[1-3]

Additional Information:

- Patients may receive reimbursement for approved travel expenses associated with participating in this study.
- People who are in the study may stop at any time.
- The likely course of your cancer may or may not improve by taking part in this study.

Reference: 1. Laine, et al. Molecular Pathways: Harnessing E2F1 Regulation for Prosenescence Therapy. *Molecular Therapy.* Vol. 10, No. 4, October 2004. **2.** Santos Apolonio J, Lima de Souza Gonçalves V, Cordeiro Santos ML, Silva Luz M, Silva Souza JV, Rocha Pinheiro SL, de Souza WR, Sande Loureiro M, de Melo FF. Oncolytic virus therapy in cancer: A current review. *World J Virol.* 2021 Sep 25;10(5):229-255. doi: 10.5501/wjv.v10.i5.229. PMID: 34631474; PMCID: PMC8474975. **3.** Chen DS, Mellman I. Oncology meets immunology: the cancer-immunity cycle. *Immunity.* 2013 Jul 25;39(1):1-10. doi: 10.1016/j.immuni.2013.07.012. PMID: 23890059.

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