

Cretostimogene grenadenorepvec

PIVOT-006 A clinical trial
for the treatment of
intermediate-risk NMIBC

PIVOT-006

PHASE 3 Clinical Trial NOW ENROLLING

Who may be eligible to take part

People with:

- bladder cancer that has not invaded the muscle (non-muscle invasive bladder cancer)
- *Intermediate Risk Disease
- Over 18

Treatment

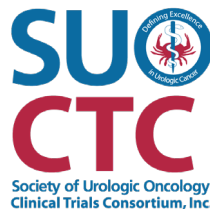
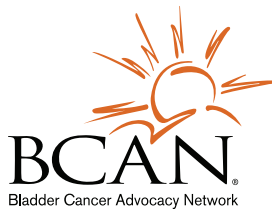
The treatment will be put into the bladder (instilled) through a tiny tube called a catheter. You will need this done 14 times over an eighteen month period of time.

Main measure

The number of people who after having their bladder cancer surgically removed and receiving the treatment (cretostimogene grenadenorepvec) and subsequently do not have cancer in their bladder.

*Intermediate Risk Bladder Cancer is when: it comes back within 1 year and it is low-grade papillary carcinoma only within the lining of the bladder (non-invasive papillary carcinoma) there is only 1 low-grade tumor and it is larger than 3 cm.

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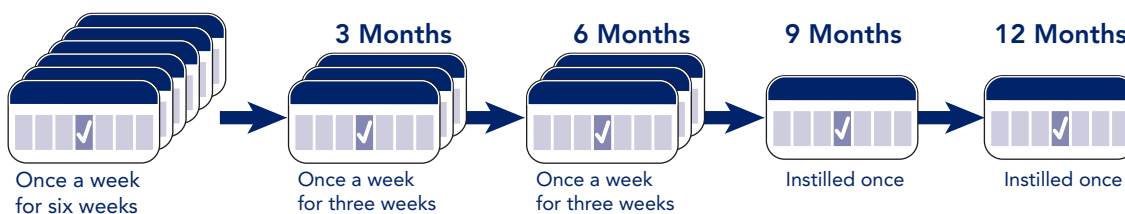
About the PIVOT-006 study:

Participants in the PIVOT-006 study will receive cretostimogene grenadenorepvec and or surgical treatment. The study is open label which means both the doctor and patient can know if the patient is receiving the treatment. The cretostimogene will be instilled into the bladder 14 times over 52 weeks.

If you are interested in learning more about the study:

- Contact recruitment@cgoncology.com
- Discuss with your Urological Oncologist – bring this information with you.
- Visit <https://clinicaltrials.gov/ct2/show/NCTXXXXXXXXXXXX>

PIVOT-006 Patient Instillation Pattern



What is the purpose of the study:

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

The use of cretostimogene grenadenorepvec described in this study and others is experimental. Because of that not all risks are known.

How does the treatment work?

We believe that the treatment drug goes into bladder cancer cells and kills them and also activates the immune system work better to kill the cancer cells.^{1,2,3}

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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