Cretostimogene grenadenorepvec

CORE-008, a phase 2, multi-arm, multi-cohort, study for treatment of High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)

Core-008)

PHASE 2 Clinical Trial COHORT A NOW ENROLLING

Who May Be Eligible to Take Part In This Study

Adults who have:

- Bladder cancer that has not invaded the muscle (NMIBC)
- High-risk NMIBC that is categorized as Carcinoma in Situ (CIS) with or without Ta or T1 disease
- Either never have had BCG treatment, received BCG over 2 years ago, or have had only 1-2 BCG doses in the last 2 years.

Treatment

Participants in the CORE-008 study will receive cretostimogene grenadenorepvec in addition to surgical standard-of-care. The treatment will be instilled into the bladder through a thin tube called a catheter.

This will be done once a week for 6 weeks* then followed by maintenance cretostimogene every 3 months for the first year and then every 6 months for up to 36 months.

* a second 6 week re-induction course will occur at three months for some patients

Main measure

Evaluate how many participants experience a complete response of their bladder cancer to cretostimogene treatment.

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About Cohort A of the CORE-008 Phase 2 Trial:

Cohort A is a randomized study of participants with CIS-containing high-risk NMIBC who have never had BCG treatment, had minimal exposure to BCG, or received BCG a long time ago. Participants will all receive surgical treatment as well as cretostimogene. Cretostimogene will be given to all study participants through a thin tube called a catheter using one of two instillation procedures, depending on the group they are assigned to.

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/NCT06567743

CORE-008 Patient Instillation Pattern



What is the purpose of the study:

The purpose of this study is to see if your bladder cancer responds to treatment with cretostimogene. People in the study will continue to be monitored by cystoscopy and pathology to see if the cancer has responded to treatment.

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 NMIBC.

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.

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:

- Participants 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.

