CRESTONE

CLINICAL STUDY OF RESPONSE TO SERIBANTUMAB IN TUMORS WITH NEUREGULIN-1 (NRG1) FUSIONS

The CRESTONE study is open and enrolling today for patients whose solid tumor was found to have an NRG1 gene fusion.

For patients who have had their tumor genomically tested (biomarker testing), they may be eligible for this study.

CRESTONE STUDY DESIGN | PHASE 2 TUMOR-AGNOSTIC TRIAL

BACKGROUND

- The purpose of this study is to test an experimental drug called seribantumab
- Seribantumab is an antibody, which is a type of protein that can locate and bind to substances in the body, including tumor cells
- Seribantumab is an antibody that binds to a specific protein found on the surface of the cells called HER3 (or ERRB3)
- This protein, HER3, is involved in cancer cell growth when activated or triggered by another protein (or biomarker) like NRG1 fusion protein
- Laboratory studies have shown that seribantumab potentially blocks NRG1 fusion protein from binding to and activating the HER3 protein, so that cancer cells do not grow

ELIGIBLE PATIENTS

- Patients aged ≥ 18 years old, with a locally advanced or metastatic solid tumor, who received and progressed after a minimum of one prior standard therapy
- Tumor must have an NRG1 fusion, determined by testing at a local CLIA or similarly accredited lab

PARTICIPANT ENROLLMENT

Cohort 1 Patients with no prior treatment with a Pan-ERBB (HER), HER2 or HER3 targeted therapy. No other actionable molecular alterations than an NRG1 fusion. Provision of tumor tissue (archived or new biopsy) for central confirmation of NRG1 gene fusion

Cohort 2 Patients who have previously been treated with a Pan-ERBB, HER2, or HER3 targeted therapy and have relapsed or are refractory to their treatment. No other actionable molecular alterations than an NRG1 fusion

Cohort 3 Patients with tumors with an NRG1 fusion without an EGF-like domain, or those with NRG1 fusions and other molecular alterations lacking standard therapeutic options, **OR** patients with insufficient tissue for central confirmation of NRG1 gene fusion status

CANCER STUDY TREATMENT

All participants will receive seribantumab administered as an intravenous (IV) medication.

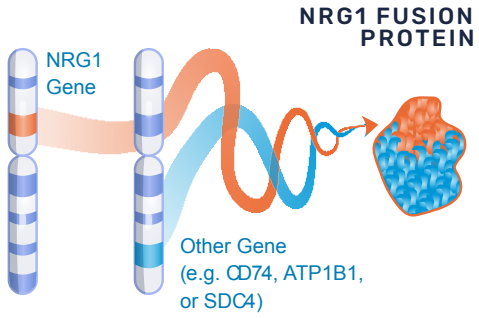
Learn more about CRESTONE at www.NRG1fusion.com
clinicaltrials.gov identifier: NCT04383210

Elevation Oncology is the sponsor of the CRESTONE trial.
Our medical staff welcomes your questions, and can be contacted at clinical@elevationoncology.com or +1 (716) 371-1125.

NRG1 Gene Fusions

NRG1 gene fusions are rare genetic alterations resulting from the fusion of the NRG1 gene with a second gene, causing production of NRG1 fusion proteins. These alterations can cause unregulated cell growth and proliferation leading to the formation of a tumor, and can be found in tumors that originate from many different cell types.

NRG1 gene fusions are considered to be oncogenic "driver alterations" and an important new therapeutic target.

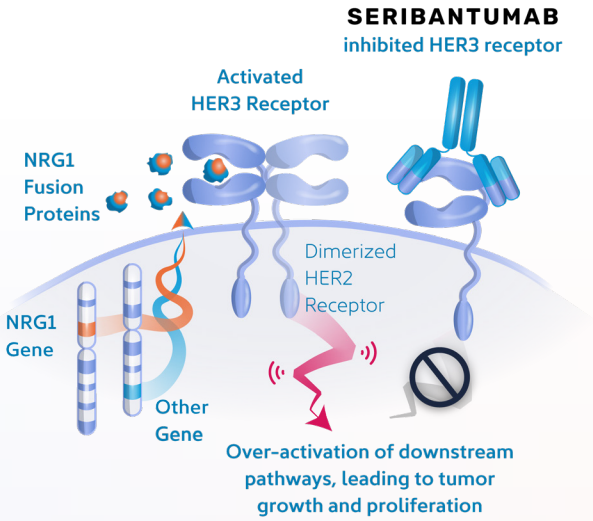


Seribantumab

(anti-HER3 IgG2 monoclonal antibody)

Seribantumab is an investigational therapy targeting HER3. NRG1 fusion proteins can bind to HER3 and cause over-activation of signals that tell a tumor cell to grow and proliferate.

Seribantumab is believed to work by preventing the NRG1 fusion protein from binding to HER3. By stopping the HER3 signaling, seribantumab may stop the driving force that sustains the tumor.



Genomic testing of your tumor is the only way to confirm if it has an NRG1 fusion

The most sensitive method of detecting an NRG1 gene fusion today is an RNA-based Next Generation Sequencing test that looks at your tumor's RNA rather than its DNA.

Ask your doctor today about your options for genomic testing, and whether you may be eligible for an approved targeted therapy or a clinical trial.

Your decision to participate in a clinical trial is voluntary and should only be made after all your questions have been answered and you have been able to make a well-informed decision.

*"While these fusions are uncommon events, **if we detect just one, it changes everything.**"*

DR. ROBERT DOEBELE, MD, PHD
Targeted Oncology, January 2020

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