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 has tested positive for an NRG1 gene fusion.

If you or your patient have already had their tumor genomically tested, you may be eligible for this study.

CRESTONE STUDY DESIGN | PHASE 2 TUMOR-AGNOSTIC TRIAL

ELIGIBLE PATIENTS

- Patients age ≥ 18 years old, with any advanced solid tumor
- Tumor must have an NRG1 fusion, determined by testing at a local CLIA or similarly accredited lab

PATIENT ENROLLMENT

Cohort 1 (Pivotal)	*55 Patients*	Patients with no prior treatment with a Pan-ERBB (HER), HER2 or HER3 targeted therapy
Cohort 2	*10 Patients*	Patients who have previously been treated with a Pan-ERBB, HER2, or HER3 targeted therapy and have relapsed or are refractory to their treatment
Cohort 3	*10 Patients*	Patients with an NRG1 fusion without an EGF-like domain **OR** Patients with insufficient tissue for central confirmatory testing

CANCER TREATMENT

All patients will receive investigational therapy, seribantumab (IV).

Seribantumab is an intravenous (IV) medication that is administered in a hospital, out-patient infusion center.

STUDY FOLLOW-UP

- NRG1 fusion status for all patients will be centrally confirmed using an RNA-based sequencing test
- An interim analysis will be conducted after 20 patients have been enrolled in Cohort 1
- Pivotal data from the study will be assessed after Cohort 1 is fully enrolled and treated:
  - **Primary endpoint:** Objective response rate (ORR) per RECIST v1.1 by independent, central radiologic review
  - **Secondary endpoints:** Duration of response (DoR), Safety, Progression free survival (PFS), Overall survival (OS), Clinical Benefit Rate (CR, PD, SD > 24 weeks)

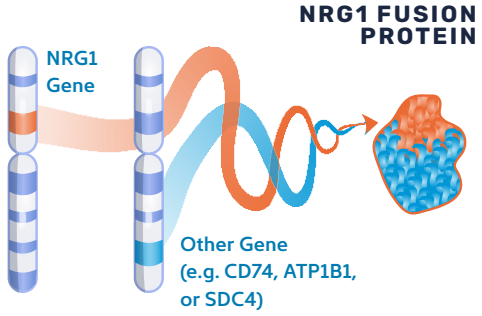
Learn more about CRESTONE
at www.NRG1fusion.com
clinicaltrials.gov identifier: NCT04383210

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

NRG1 Fusions

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

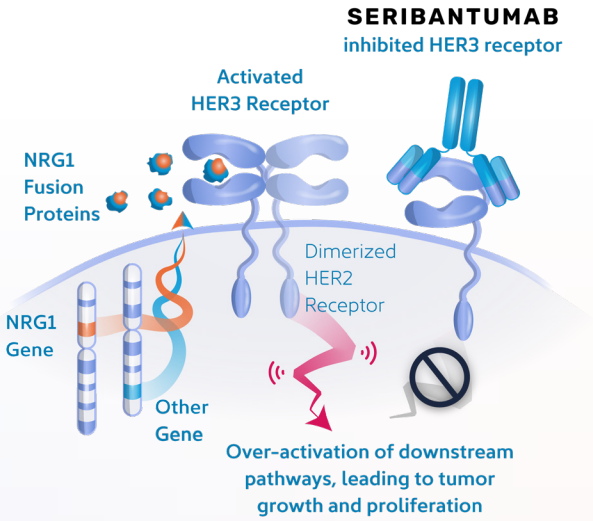


Seribantumab

(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 (NGS) 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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