A multicenter, open-label, non-randomized, phase 1b trial of NG-350A, a tumor-selective anti-CD40-expressing adenoviral vector, in combination with chemoradiotherapy in locally advanced rectal cancer (FORTRESS).

Study Design

The FORTRESS trial (NG-350A-03) combines the cancer-specific virus NG-350A in with chemotherapy and radiotherapy in patients with locally advanced rectal cancer. The study is open to patients with at least one risk factor for local or distant recurrence. This trial is designed to assess whether NG-350A can improve treatment responses to chemotherapy and radiotherapy.

The effect of NG-350A plus chemotherapy and radiotherapy can be assessed during the 12-week active study treatment period without compromising the ability of participating institutions to deliver additional standard-of-care treatment, including additional chemotherapy and/or surgery, during the trial follow-up period.

Patients will receive a maximum of 3 cycles of NG-350A, with each cycle consisting of NG-350A infusions on Days 1, 3, and 5 of each 4-week cycle (with viral dosing thus scheduled on Weeks 1, 5, and 9). Patients will also receive 5 weeks of chemotherapy and radiotherapy, scheduled from Weeks 2 to 6.

After the 12-week treatment period, only two follow up visits are required. These visits, to further assess clinical response, will occur 18 and 36 weeks from the time a patient receives their first dose of NG-350A.

Endpoints (what is being measured in the study):

- Safety: How often patients have adverse reactions
- Tolerability: How often the administration of treatment needs to be modified or discontinued.
- Pharmacodynamic effects: Effects of the treatment on the patient's body.
- Effect on tumor: The amount of tumor reduction due to the treatment.

Eligible patients must meet certain criteria including:

- Male or female adult patients (≥18 years of age) with locally advanced rectal cancer and the risk of local or distant recurrence.
- Histologically confirmed clinical stage II-III adenocarcinoma of the rectum with at least one pre-specified risk factor for recurrence.
- Selected by a multidisciplinary team for treatment with a disease management strategy beginning with chemotherapy and radiotherapy (which may be followed by additional chemotherapy and/or surgery).

Participating Sites:

- **Ohio State University Comprehensive Cancer Center – *Columbus, Ohio***
- **MD Anderson Cancer Center – *Houston, Texas* (planned site, pending activation)**
- **UCSF Helen Diller Family Comprehensive Cancer Center – *San Francisco, California* (planned site, pending activation)**

More information about this study is available for patients or physicians at
FORTRESS Study Details | ClinicalTrials.gov
For additional assistance, please reach out to robert.maietta@akamisbio.com
For more information about Akamis Bio, visit www.akamisbio.com