

NG-350A Plus Chemoradiotherapy for Locally Advanced Rectal Cancer

NCT06459869

Status	RECRUITING
Phase	Phase 1
Sponsor	Akamis Bio
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (8)

- Histologically confirmed adenocarcinoma of the rectum.
- Locally advanced disease (clinical stage II-III based on pelvic MRI) selected by a multidisciplinary team for treatment with neoadjuvant CRT (which may be followed by CNCT to comprise planned TNT). Patients with oligometastatic disease are permitted provided that the site-specific multidisciplinary team deems them suitable for radical treatment/chemoradiation.
- Confirmed microsatellite stable (MSS)/proficient mismatch repair (pMMR) status.
- Provide written informed consent to participate.
- ECOG Performance Status 0 or 1.

... and 3 more (see full listing online)

Exclusion (15)

- Recurrent rectal cancer.
- Distant metastatic disease not amenable to radical treatment/chemoradiation.
- Other prior malignancy active within the previous 3 years, except for local or organ confined early-stage cancer that has been definitively treated with curative intent, does not require ongoing treatment, has no evidence of residual disease, and has a negligible risk of recurrence and is therefore unlikely to interfere with the primary and secondary endpoints of the trial, including response rate and safety.
- Splenectomy (patients with prior partial resection remain eligible if the Investigator considers splenic function to not be significantly compromised).
- Active autoimmune disease that has required systemic therapy in the past 2 years, immunocompromised status in the opinion of the Investigator, or current treatment with systemic immunosuppressive therapy (daily prednisone equivalent for chronic system replacement not to exceed 10mg per day).

... and 10 more (see full listing online)

Locations (6 total)

AdventHealth Orlando, Orlando, Florida, United States
Washington University School of Medicine, St Louis, Missouri, United States
Ohio State University Comprehensive Cancer Center, Columbus, Ohio, United States
... and 3 more locations

<https://clinicaltrials.gov/study/NCT06459869>

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