

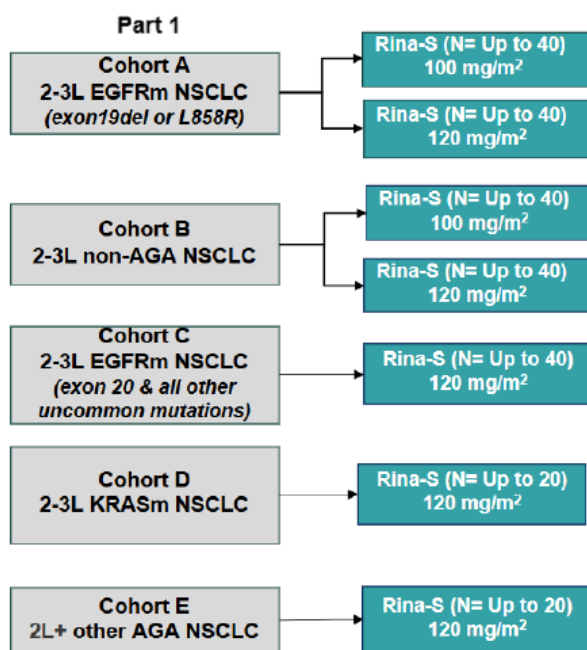
GCT1184-05 (Genmab)

A Phase 2, Open-label, Multicohort Study of Rinatabart Sesutecan (Rina-S) in Participants with Non-Small Cell Lung Cancer.

This is the trial summary as assessed on clinicaltrials.gov. You can check this on this direct link:

[Study Details](#) | [NCT05579366](#) | [Rinatabart Sesutecan \(Rina-S, PRO1184, GEN1184\) for Advanced Solid Tumors \(GCT1184-01/ PRO1184-001\)](#) | [ClinicalTrials.gov](#)

Trial Design:



Abbreviations: 2L=second line; 3L=third line; AGA=actionable genomic alteration(s); EGFRm=epidermal growth factor receptor-mutated; exon19del=exon 19 deletion; KRAS=Kirsten rat sarcoma viral oncogene homologue; NSCLC=non-small cell lung cancer; Q3W=every 3 weeks; Rina-S=rinatabart sesutecan.

Inclusion criteria:

All study cohorts (Part 1):

- Participant has histologically or cytologically confirmed metastatic or locally advanced NSCLC of adenocarcinoma histology, not amenable to curative surgery or radiotherapy.
- Participant must have radiological disease progression while on or after receiving the most recent regimen.

Cohort A:

Participant who prior to this study has been treated with at least one but no more than two prior lines of therapy that was administered due to presence of an EGFR-activating mutation (ex19del or L858R mutation) as assessed with an FDA-approved test or other validated tests, consisting of:

- One platinum-containing chemotherapy regimen, concurrently or sequentially with a third generation EGFR tyrosine kinase inhibitor (TKI); or
- Up to two prior line(s) of an approved EGFR-targeted therapy in the metastatic or locally advanced setting, including platinum-doublet chemotherapy concurrently or sequentially.

Cohort B:

Participant who prior to this study has been treated with at least one but no more than two prior lines of therapy that was administered due to the absence of AGA, for which no targeted therapy has been identified, or such treatment is not available to the participant (not approved and/or reimbursed), as assessed with an FDA-approved test or other validated tests, consisting of:

- One prior line of therapy (platinum-based chemotherapy and programmed cell death protein 1 [PD-1]/programmed death-ligand 1 [PD-L1] inhibitor \pm anti-cytotoxic T-lymphocyte associated protein 4 [CTLA-4], if administered concurrently) in the metastatic disease setting; or
- No more than 2 prior lines of therapy (PD-1/PD-L1 inhibitor [\pm anti-CTLA-4] and platinum-based chemotherapy, if administered sequentially) in the metastatic disease setting

Cohort C:

Participant who prior to this study has been treated with at least one but no more than two prior lines of therapy that was administered due to the presence of an EGFR ex20ins or other non-ex20ins uncommon single or compound EGFR mutation (excluding C797S) as assessed with an FDA-approved test or other validated tests, consisting of:

- Targeted therapy, eg, afatinib, amivantamab monotherapy, or an amivantamab-containing regimen (if locally available); and/or
- One platinum-containing chemotherapy regimen

Cohort D:

Participant who prior to this study has been treated with at least one but no more than two prior lines of therapy that was administered due to the presence of a KRAS mutation as assessed with an FDA-approved test or other validated tests, consisting of:

- Prior treatment with PD-1/PD-L1 inhibitor and platinum-based chemotherapy concomitantly or sequentially in the metastatic disease setting, and treatment with an approved targeted agent in case of KRAS G12C mutation.

Cohort E:

Participant who prior to this study has been treated with at least one prior line of treatment in the advanced/metastatic setting containing an approved targeted therapy for respective genomic alteration which was detected with an FDA-approved test or other validated tests, and platinum-based chemotherapy (with or without immunotherapy) if the AGA was detected during that line of treatment.

Exclusion criteria:

- Participant has NSCLC with histology other than adenocarcinoma
- Participant has a past or current malignancy other than the inclusion diagnosis before the planned first dose of trial treatment, or any evidence of residual disease from a previously diagnosed malignancy. Exceptions are malignancies with a negligible risk of metastasis or death (eg, 5-year OS \geq 90%), including, but not limited to, adequately treated cervical carcinoma of stage 1B or less, in situ basal cell or squamous cell skin carcinoma, in situ bladder cancer, ductal carcinoma in situ, or any past malignancy considered cured for \geq 3 years.
- Participants with newly identified or known unstable (eg, progressing brain metastases) or symptomatic central nervous system (CNS) metastases or history of carcinomatous meningitis (also known as leptomeningeal disease). Participants with history of spinal cord compression (from disease). Participants with previous CNS-directed therapy (eg, radiotherapy and/or surgery) for brain metastases may participate provided lesion(s) are radiologically stable (ie, without evidence of progression) for at least 28 days by repeat imaging.