

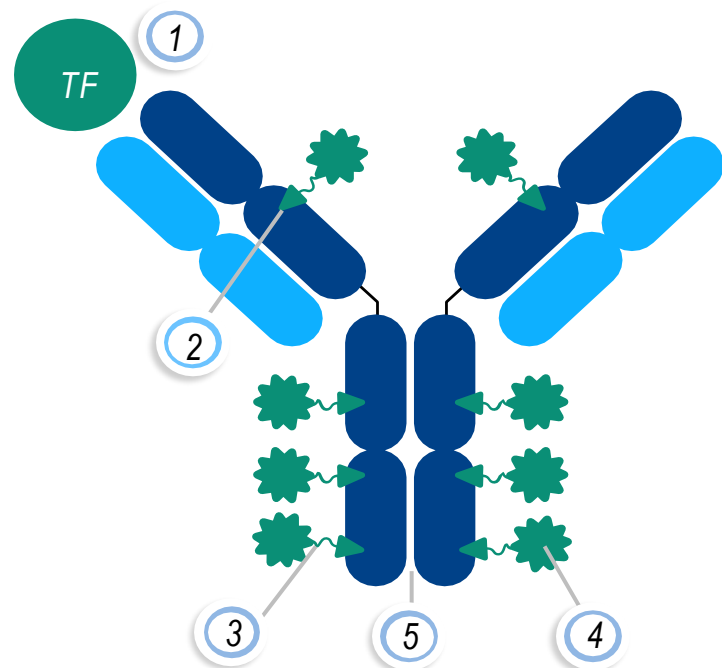


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Background

- Tissue Factor (TF), a transmembrane glycoprotein with tumor-selective expression, has been implicated in promoting tumor progression through enhanced tumor angiogenesis and metastasis.¹
- TF is overexpressed on the cell surface of multiple solid tumors.²
- STRO-004 is a novel TF-targeted ADC with a drug-antibody ratio (DAR)=8.
- Preclinical data demonstrate potent anti-tumor activity across TF-expressing tumor models, including those with heterogenous or low TF expression.
- STRO-004 also induces immunogenic cell death (ICD), activating antigen-presenting cells (APCs) and potentially driving durable anti-tumor immunity. These findings support combination with immunotherapies.
- The highest non-severely toxic dose (HNSTD) in preclinical studies was 50 mg/kg

STRO-004



1 Enhanced mAb with high affinity, internalization; reduced bleeding risk

2 Optimally positioned non-natural amino acids, p-azidomethyl-L-phenylalanine (pAMF), combined with ultra stable click chemistry results in lowest levels of unconjugated payloads

3 β-glucuronidase cleavable linkers with tumor selective cleavage, strong stability while in circulation, and added hydrophilicity led to best-in-class PK

4 Exatecan payload causing DNA disruption and potent tumor cell killing, with high bystander activity, and immunogenic cell death (ICD)

5 Lack of FcγR interactions limits uptake by alveolar macrophages, reducing risk of interstitial lung disease (ILD)

Study Design

- STRO-004-ST1 is a first-in-human, Phase 1, open-label, multicenter study evaluating the safety, PK, and anti-tumor activity of STRO-004 in adults with refractory or recurrent metastatic solid tumors. (NCT07227168)
- Part 1A Monotherapy Dose Escalation
- Part 1B Monotherapy Cohort Expansion
- Part 1C Combination Dose Escalation with pembrolizumab
- Part 1A endpoints include maximum tolerated dose (MTD), dose-limiting toxicity (DLT), anti-tumor activity and PK; efficacy is the primary endpoint in Part 1B. Exploratory endpoints include determining predictive biomarkers of response and biomarkers of activity and resistance
- For dose escalation, the Modified Toxicity Probability Interval 2 (mTPI-2) design will be utilized.
- Approximately 200 patients will be enrolled.**

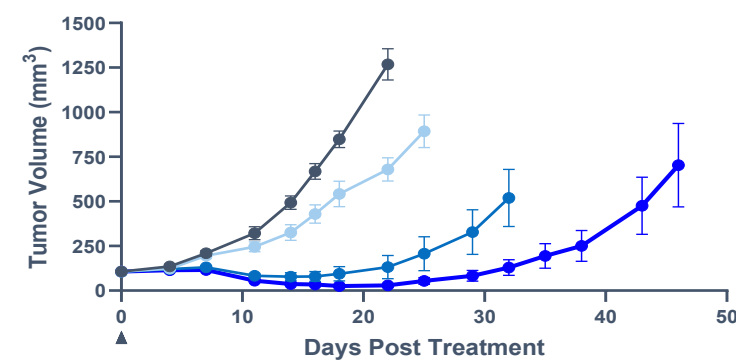


Tumor types were selected for known TF expression

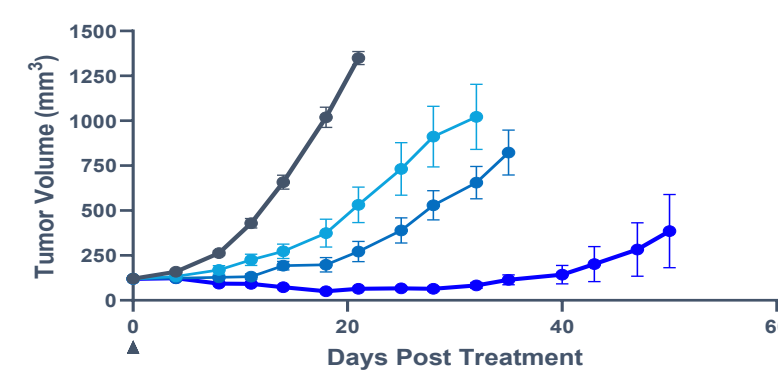
Preclinical Results

- STRO-004, a DAR-8 exatecan ADC, achieved sustained tumor regressions in xenograft models of NSCLC and HNSCC at low doses

Lung (TF+++) H1975 Growth Curves



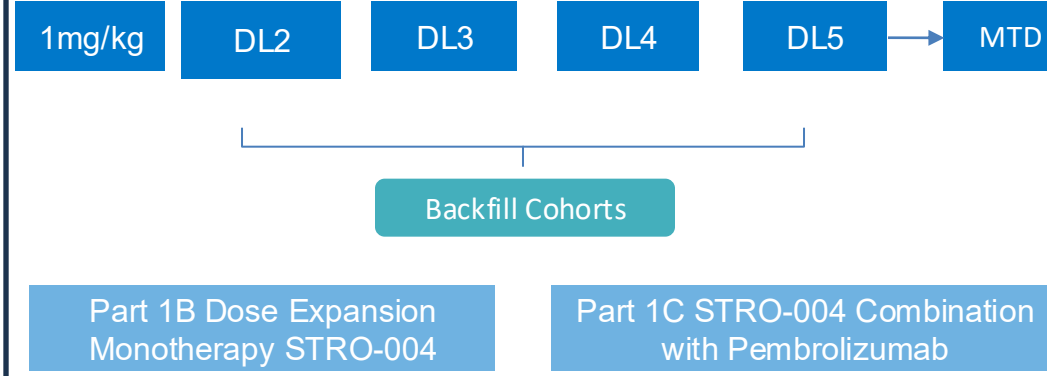
Head and Neck (TF++) Detroit562 Growth Curves



Legend: Vehicle (black), STRO-004, 0.125 mg/kg (light blue), STRO-004, 0.25 mg/kg (medium blue), STRO-004, 0.5 mg/kg (dark blue), STRO-004, 1 mg/kg (purple)

Study Schema

Part 1A Dose Escalation STRO-004 I.V. Q 3 weeks



Key Eligibility

Inclusion Criteria

- Solid tumors including: HNSCC, NSCLC, Esophageal, Gastric, CRC, PDAC, Cervical cancer, Endometrial cancer, and Urothelial cancer
- Received all appropriate systemic therapies
 - Dose Escalation (Parts 1A and 1C): No limit on the number of prior therapies
 - Expansion Phase (Part 1B): Up to 3 prior therapies are allowed. For participants with actionable genomic alterations (AGA)-driven adenocarcinoma NSCLC up to 4 prior therapies are allowed.
- Availability of tissue for retrospective immunohistochemistry determination of TF expression
- Measurable disease per RECIST 1.1
- Treatment with anticoagulants allowed, if dose is stable

Exclusion Criteria

- Prior treatment with an ADC with a TOPO-I payload or a TF ADC, other than the approved TF ADC, tisotumab vedotin
- Pre-existing clinically significant ocular surface disorders
- Untreated or active brain metastases and/or leptomeningeal disease. Treated brain metastases, stable for a minimum of 4 weeks prior to enrollment, are allowed.
- Active interstitial lung disease or active, non-infectious pneumonitis or a history of active pneumonitis ≤ 6 months from C1D1
- HIV positive patients are eligible if they are on treatment with adequately controlled viral load

Accrual and Study Sites

- The study is currently open at 8 sites in the United States
- Enrollment began in Q4 2025 and is ongoing

Study Assessments

Safety

- Frequent assessment during the first 3 weeks of treatment and at least every 3 weeks thereafter
- Safety evaluations include assessments of AEs, vital signs, electrocardiograms, laboratory tests, concomitant medications, and regular ophthalmologic exams
- Potential ADC-associated AEs to be monitored include ocular, pulmonary, neurological, skin, and bleeding

Tumor Assessments

- Tumor status will be evaluated by contrast-enhanced MRI and/or CT with treatment response assessed according to RECIST v1.1 by investigator
- CT of chest/abdomen/pelvis or CT of chest and MRI of abdomen/pelvis will be performed at baseline, every 6 weeks through Week 42, and every 9 weeks thereafter

Overall Survival Follow-up Assessments

- Every 12 weeks for at least 1 year

Pharmacokinetic and Immunogenicity Assessments

- Blood samples will be obtained based on a protocol specified schedule to assess the PK STRO-004, total antibody, and free payload during treatment and post-treatment; blood samples for assessment of immunogenicity (anti-drug antibody analysis) will be collected using a similar schedule

Biomarkers

- TF expression will be assessed from archival or fresh tumor at baseline and during treatment (optional)
- Blood-based tumor markers will also be evaluated

Conclusions

- STRO-004 is a TF-targeting ADC with potential to improve efficacy and enhance tolerability
- Preclinical data support broad antitumor activity
- This phase 1 study will define the safety, PK and preliminary anti-tumor activity of STRO-004 as monotherapy and in combination with pembrolizumab
- Results will inform dose selection and future clinical development
- STRO-004-ST1 is actively enrolling in the United States
- Initial data from dose escalation expected mid 2026
- Please see abstract presentation # 4446 for additional STRO-004 pre-clinical data
- Study and poster development support provided by Sutro Biopharma