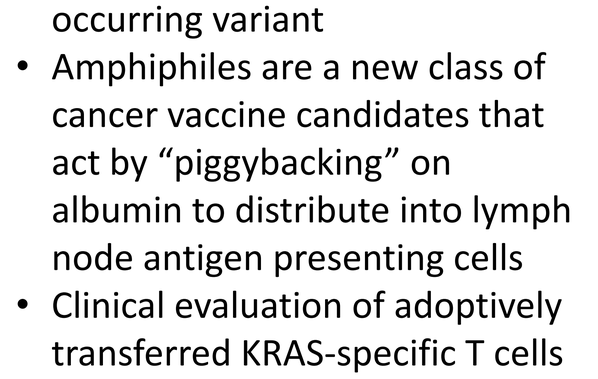
# TPS2701: First in human phase I trial of ELI-002 immunotherapy as treatment for subjects with Kirsten Rat Sarcoma (KRAS) mutated pancreatic ductal adenocarcinoma and other solid tumors (trial in progress)

Shubham Pant[1], Muhammad Furqan[2], Raghad Abdul-Karim[3], Vincent Chung[4], Craig Devoe[5], Melissa Johnson[6], Alexis Leal[7], Haeseong Park[8], Zev Wainberg[9], Esther Welkowsky[10], Christopher Haqq[10], Eileen M. O'Reilly[11], Colin Weekes[12]

City of Hope, Duarte, CA[4], Elicio Therapeutics, Boston, MA[10], Henry Ford Health System, Detroit, MI[3], Massachusetts General Hospital, Boston, MA[12], Memorial Sloan Kettering Cancer Center, New York, NY[11], Northwell Health, Lake Success, NY[5], Tennessee Oncology, Nashville, TN[6], University of California, Los Angeles, Los Angeles, CA[9], University of Colorado, Aurora, CO[7], University of Iowa, Iowa City, IA[2], University of Texas, MD Anderson Cancer Center, Houston, TX[1], Washington University School of Medicine, St. Louis, MO[8]

## Background

- Mutations in the RAS oncogenes KRAS, NRAS and HRAS occur in one quarter of solid cancers
- G12D is the most commonly occurring variant
- Amphiphiles are a new class of cancer vaccine candidates that act by "piggybacking" on albumin to distribute into lymph node antigen presenting cells
- Clinical evaluation of adoptively transferred KRAS-specific T cells demonstrated objective antitumor activity (Tran et al., NEJM 2016).
- Circulating tumor DNA and serum tumor biomarkers permit identification of patients with minimal residual disease (MRD)
- In preclinical models, ELI-002 demonstrated 60-400X increased cytotoxic KRAS-specific T cells compared to non-lymph node targeted controls using the same peptides and adjuvant:




## Hypotheses

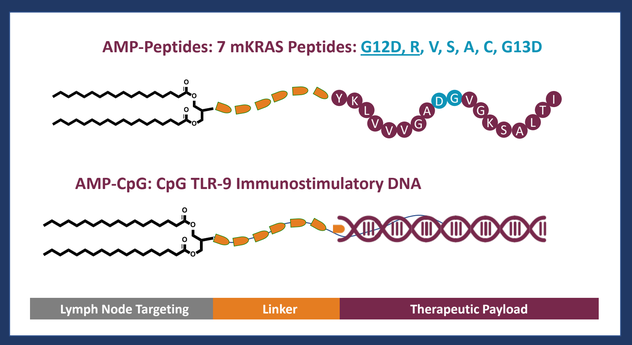
- Immunotherapy is anticipated to succeed in MRD setting since the ratio of effector T cells to target tumor cells is maximized prior to bulk visible disease
- ELI-002 is safe and the maximum tolerated dose (MTD) and/or recommended phase 2 dose can be established at the end of phase 1 dose escalation

References

- Liu et al., Nature 2014
- Moynihan et al., Nature Medicine 2016
- Moynihan et al., Cancer Immunology Research 2018
- Ma et al., Science, 2019
- Singh and June, Science, 2019
- Steinbuck et al., Science Advances 2021

## The AMPLIFY trial: lymph node targeted vaccine ELI-002 in patients with RAS mutated tumors at risk for relapse after locoregional treatment

- ✓ *KRAS tumor mutation G12D, G12R, G12V, G12C, G12A, G12S or G13D positive*
- ✓ *ctDNA or serum tumor biomarker positive despite prior standard treatment for locoregional disease*
- ✓ *pancreatic adenocarcinoma, colorectal, NSCLC, ovarian, biliary or gallbladder*
- ✓ *ECOG 0 or 1*
- ❖ *Tumor mutations with approved therapy*
- ❖ *Use of immunosuppressive drugs*




ELI-002 is comprised of 7 mutated KRAS/NRAS Amphiphile (AMP)-peptides combined with Amphiphile (AMP) -CpG danger signal TLR9 activator

Shubham Pant, MD (spant@mdanderson.org) (Abstract TPS2701)

Presented at ASCO22 Annual Meeting June 3-7, 2022

Acknowledgements: Funding for this study is provided by Elicio Therapeutics, Inc.

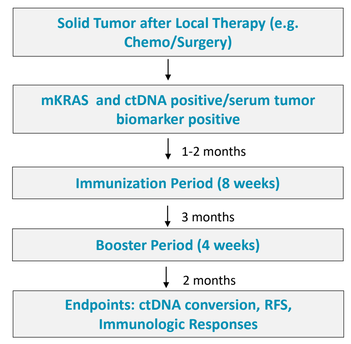
## Study Design

- Open label, dose-escalation and expansion phase 1 first-in-human
- Patients receive fixed doses of AMP-peptide 70 mcg each, together with escalating doses of AMP-CpG in a standard 3+3 design
- RP2D will expand to ≥ 6 patients

| | AMP-CpG | AMP-KRAS-Peptides |
|---|---|---|
| Cohort 1 | **0.1 mg** | **70 mcg each** |
| Cohort 2 | **0.5 mg** | **70 mcg each** |
| Cohort 3 | **2.5 mg** | **70 mcg each** |

## Treatment

- Patients receive 6 ELI-002 doses in the immunization period
- After 3 month off treatment, patients receive 4 additional ELI-002 doses in the Booster Period
- Follow up continues x 18 months




- Response evaluations
  - ctDNA and serum tumor biomarker change from baseline
  - ~Every 8-week CT scan imaging
  - Baseline and visit 9 pheresis for T cell mechanism of action biomarkers

## Study Objectives

- Primary: safety/tolerability, maximum tolerated dose MTD (in the event there is an MTD) and recommended phase 2 dose
- Secondary: tumor biomarker reduction/clearance
- Exploratory: relapse free survival, mechanism of action biomarker to assess T cell activation

## Study Information

- **Status:** Recruiting
- Cohort 1 has been completed with no DLT. Enrollment to Cohort 2 is open.
- **ClinicalTrials.gov:** NCT04853017