

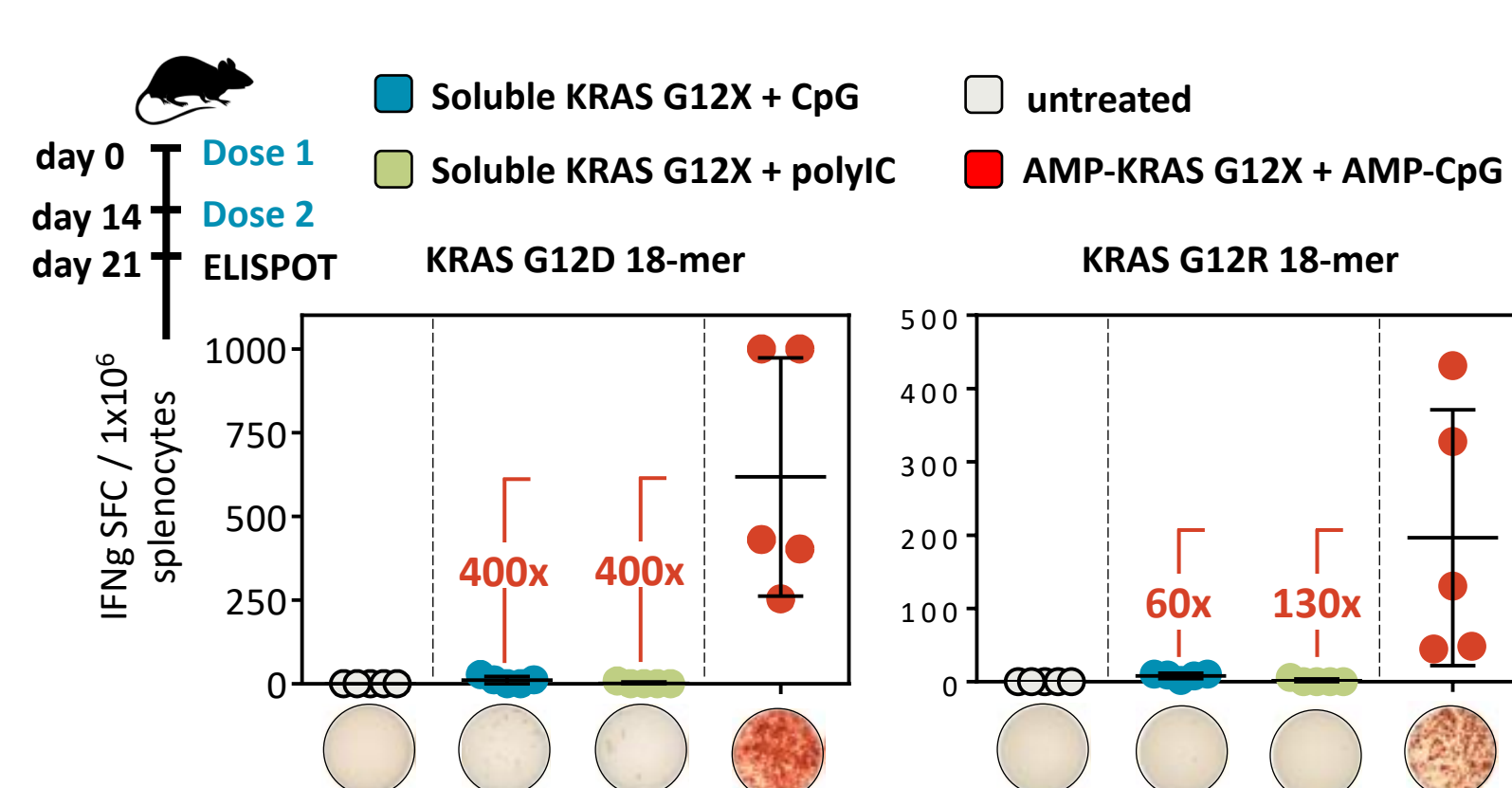
# TPS2701: First in human phase I trial of ELI-002 immunotherapy as treatment for subjects with Kirsten Rat Sarcoma (KRAS) mutated pancreatic ductal adenocarcinoma and other solid tumors (trial in progress)

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

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

## 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

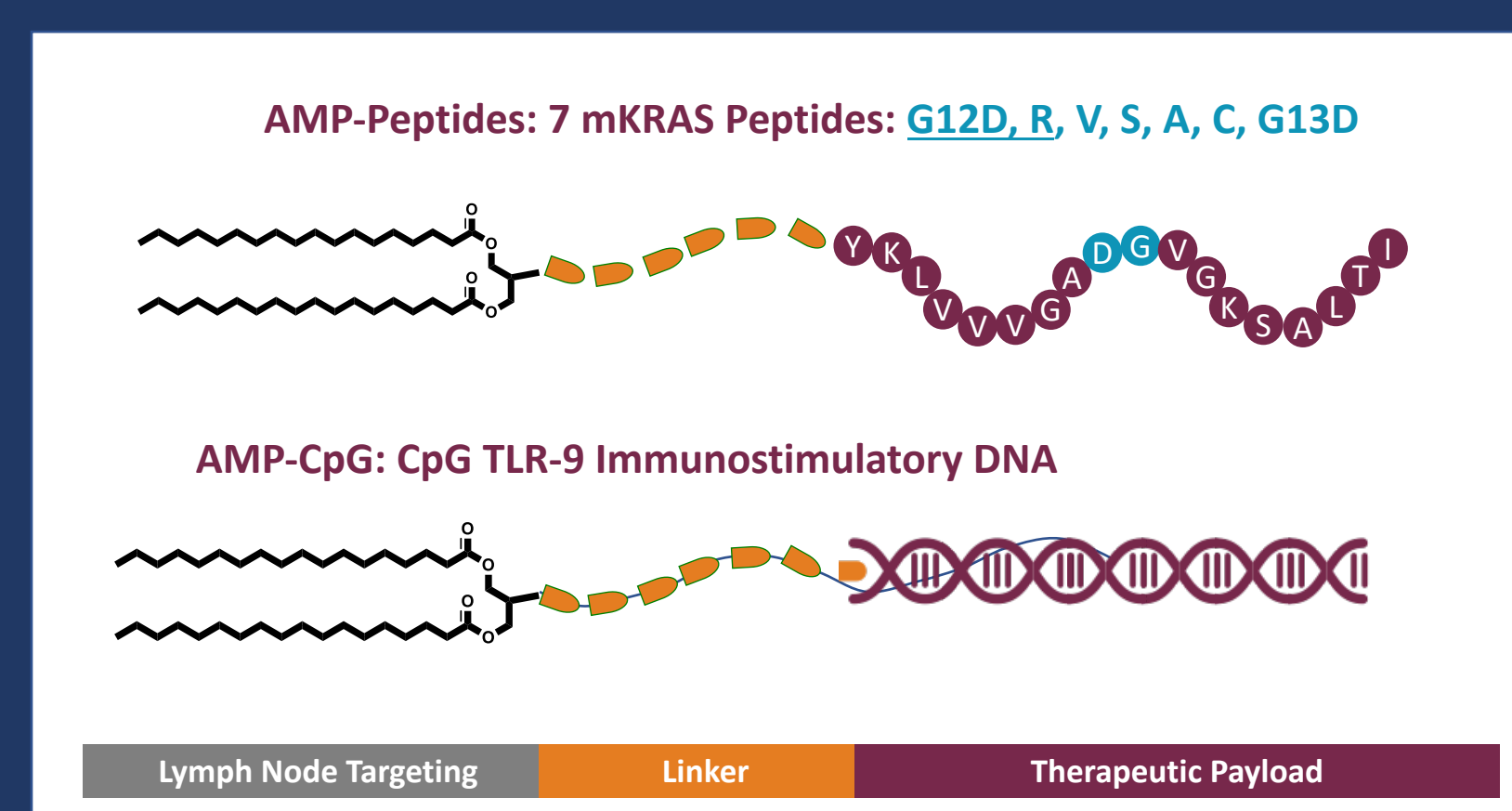
- Immunotherapy is anticipated to succeed in MRD setting since the ratio of effector T cells to target tumor cells is maximized prior to bulk visible disease
- ELI-002 is safe and the maximum tolerated dose (MTD) and/or recommended phase 2 dose can be established at the end of phase 1 dose escalation

## 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](mailto:spant@mdanderson.org)) (Abstract TPS2701)

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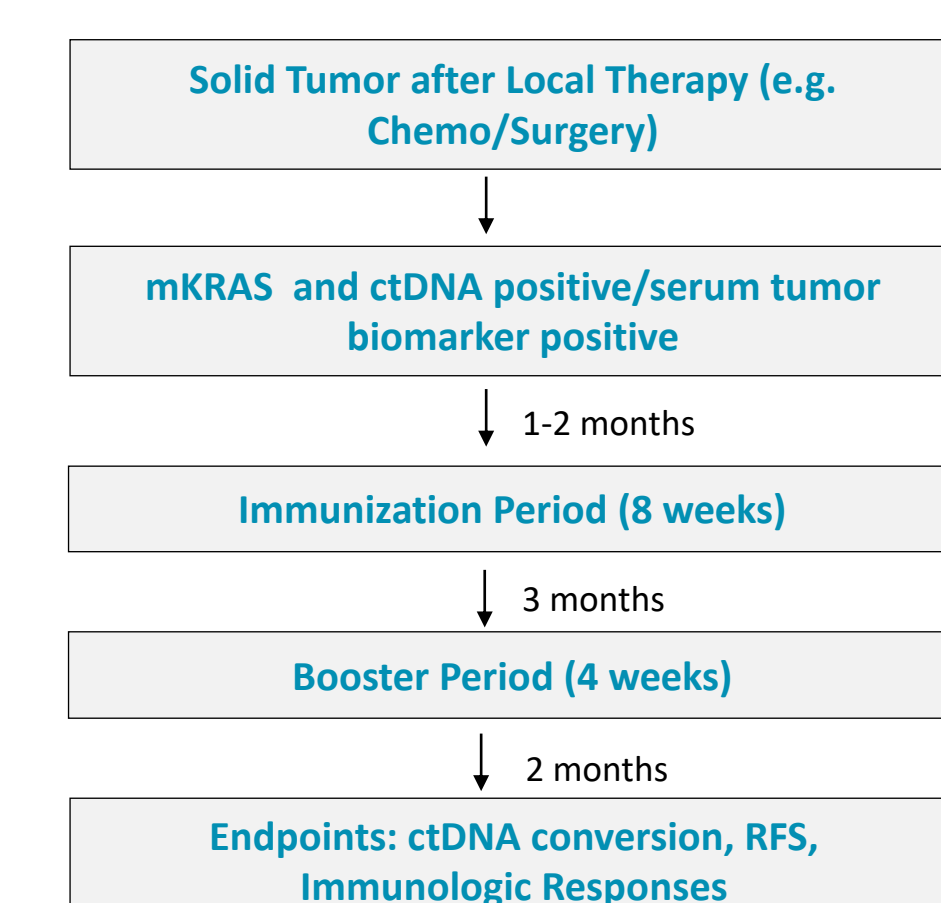
## Study Design

- 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  $\geq 6$  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