

**Elicio Therapeutics Presents Design of Ongoing AMPLIFY-201 Study in mutant KRAS-Driven Cancers at ASCO Annual Meeting 2022**

- *AMPLIFY-201 is a Phase 1 clinical study of ELI-002, a lymph node-targeted therapeutic cancer vaccine, in patients with mKRAS-driven cancers; the first patient was dosed at MD Anderson*
- *The novel study (NCT04853017) is designed to examine how to treat patients following surgical resection and standard chemotherapy for localized tumors who are at high risk for relapse*
- *It employs biomarkers for the detection of persistent circulating tumor DNA in patients at high risk for relapse but before a tumor is detected in traditional radiographic scans; Maximizing the ratio of ELI-002-induced T cells to residual tumor cells may increase efficacy*
- *Study design leverages advances in biomarker technology to create a new approach to development of cancer immunotherapy that could potentially be accelerated*

BOSTON, May 27, 2022 – [Elicio Therapeutics](#), a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer and other diseases, today announced it is presenting a poster on the AMPLIFY-201 study design at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting, being held in-person from June 3-7, 2022, in Chicago. AMPLIFY-201 is a Phase 1 study evaluating the safety and efficacy of ELI-002, a lymph node-targeted therapeutic cancer vaccine, as a treatment for patients with mKRAS-driven tumors who have minimal residual tumor cells following surgery to remove the tumor.

“Our novel study design takes advantage of recent advances in therapy response monitoring to rapidly assess the clinical activity of ELI-002 as an adjuvant therapy in patients with early-stage mKRAS-driven cancers who have minimal residual disease following surgery and chemotherapy,” said [Christopher Haqq](#), M.D., Ph.D., Elicio’s Executive Vice President, Head of Research and Development, and Chief Medical Officer. “The AMPLIFY-201 study is also looking at an extensive set of mechanism-of-action biomarkers to assess the number and function of T cells that can target tumors harboring mutations in RAS oncogenes.”

Cancers with RAS mutations account for 25% of human solid tumors. In the Phase 1 AMPLIFY-201 study, ELI-002 targets two of the KRAS mutations, G12R and G12D, the most commonly occurring variant in pancreatic, colorectal, non-small cell lung, ovarian, biliary and gallbladder cancers. The proprietary AMP technology allows for ELI-002 to ‘educate’ T cells to recognize the G12R and G12D KRAS mutations, which allows them to then target these cancers for elimination. Most other mKRAS-targeted therapeutics in development — particularly small molecule mKRAS inhibitors — are only able to target one or two KRAS mutations. Elicio is developing a broad spectrum 7-peptide formulation of ELI-002.

[Robert Connelly](#), Chief Executive Officer at Elicio, added, “We are pioneering a new approach to develop cancer immunotherapies with the AMPLIFY-201 study design that allows us to validate the clinical activity of ELI-002 with the two peptides more efficiently before bridging to the seven-



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peptide formulation targeting seven of the most common KRAS mutations in a Phase 1b/2 trial with a more traditional endpoint of Relapse-Free Survival. We look forward to sharing data from the AMPLIFY-201 study in the coming months.”

### **About AMPLIFY-201**

AMPLIFY-201 is a Phase 1 clinical trial of ELI-002 in patients with solid tumors, including colorectal cancer (CRC), pancreatic ductal adenocarcinoma (PDAC) and non-small cell lung cancer (NSCLC). The AMPLIFY-201 trial is being conducted at multiple sites, including U.S. cancer treatment institutions such as MD Anderson, Memorial Sloan Kettering, Massachusetts General Hospital, City of Hope, Washington University St. Louis, and Henry Ford Health System. Following an initial dose escalation phase, we intend to continue to evaluate the potential of ELI-002 as a treatment for a number of KRAS-mutated cancers. AMPLIFY-201 is strategically constructed to target patients with minimal residual disease, or MRD, a stage where tumor burden and immunosuppressive effects within the tumor are lower. The Phase 1/2 trial employs an investigational *in vitro* diagnostic device, or IVD, that is intended to detect circulating tumor DNA, or ctDNA, and identify patients who show signs of minimal residual disease in their blood before relapse is detected in traditional radiographic scans.

The purpose of the Phase 1 multi-center, dose-escalation study is to evaluate the safety and preliminary efficacy of ELI-002 in patients with mKRAS-driven cancers with minimal residual disease following surgery to remove the tumor. Each cohort will receive escalating doses of ELI-002 to determine safety and tolerability and to assess preliminary antitumor activity. The primary endpoints are, to define the maximum tolerable dose (MTD), recommended Phase 2 dose (RP2D), and incidence of adverse events (AE). The secondary endpoint is ctDNA response rate. The exploratory endpoints are median RFS and median overall survival (OS) among other endpoints. Please refer NCT04853017 on [clinicaltrials.gov](https://clinicaltrials.gov) for additional clinical trial information.

Endpoints including safety, determination of maximum tolerated dose, ctDNA change from baseline, relapse-free survival and immunological responses including lymph node enlargement, cytokine activity and immune response will be assessed. We anticipate initial safety, dose escalation, and correlative biomarker data from the Phase 1 portion of the trial to be available by the first half of 2022.

### **About ELI-002**

ELI-002 is a structurally novel investigational AMP therapeutic vaccine targeting mutant KRAS-driven cancers. KRAS mutations are among the most prevalent human cancers. KRAS mutations drive 32% of lung cancers, 40% of colorectal cancers and 85% to 90% of pancreatic cancer cases. ELI-002 is comprised of AMP-modified mutant KRAS peptide antigens and ELI-004, an AMP-modified immune-stimulatory oligonucleotide CpG adjuvant. The AMP mKRAS peptides and AMP CpG are targeted to the lymph node where they can potentially enhance the action of key immune cells.

ELI-002 is currently being studied in a Phase 1 trial (AMPLIFY-201) in patients with early-stage mKRAS-driven solid tumors, following surgery and chemotherapy. Enrollment in the Phase 1 study continues, following the dosing of the first patient at MD Anderson in October 2021, with the expectation to move from Cohort 2 to Cohort 3 in this quarter, and the Phase 1b/2 trial planned for early 2023. This trial will study the broad spectrum 7-peptide formulation of ELI-002. This formulation is designed to provide immune response coverage against seven of the most common

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KRAS mutations, thereby increasing the potential patient population for ELI-002 and potentially reducing the chance of bypass resistance mechanisms.

### **About the Amphiphile Platform**

Our proprietary Amphiphile, or AMP, platform delivers investigational immunotherapeutics directly to the “brain center” of the immune system – the lymph nodes. We believe this site-specific delivery of disease-specific antigens, adjuvants and other immunomodulators may efficiently educate, activate and amplify critical immune cells, potentially resulting in induction and persistence of potent adaptive immunity required to treat many diseases. In preclinical models, we have observed lymph node-specific engagement driving therapeutic immune responses of increased magnitude, function and durability. We believe our AMP lymph node-targeted approach will produce superior clinical benefits compared to immunotherapies that do not engage the lymph nodes.

Our AMP platform, originally developed at the Massachusetts Institute of Technology, or MIT, has broad potential across cancers, infectious diseases and other disease indications to advance a number of development initiatives through internal activities, in-licensing arrangements or development collaborations and partnerships.

The Amphiphile platform has been shown to deliver immunotherapeutics directly to the lymph nodes by latching on to the protein albumin, found in the bloodstream, as it travels to lymphatic tissue. In preclinical models, we have observed lymph node-specific engagement driving therapeutic immune responses of increased magnitude, function and durability.

### **About Elicio Therapeutics**

Elicio Therapeutics is a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer and other diseases. By combining expertise in immunology and immunotherapy, Elicio is engineering investigational Amphiphile immunotherapies that are intended to precisely target and fully engage the lymph nodes, the site in our bodies where the immune response is orchestrated. Elicio is engineering lymph-node-targeted AMPLifiers, immunomodulators, adjuvants and vaccines for an array of aggressive cancers and infectious diseases.

Elicio began dosing subjects in AMPLIFY-201, its Phase 1/2 clinical trial in solid tumor subjects for its lead Amphiphile vaccine, ELI-002, targeting mKRAS-driven cancers in October 2021. The Amphiphile platform emerged from the laboratories of Darrell Irvine, Howard Hughes Investigator and Professor of Biomedical Engineering in the Koch Institute of Integrative Cancer Research at MIT. For more information, please visit <https://elicio.com/>.

### **Cautionary Note on Forward-Looking Statements**

This press release includes forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties, assumptions and other important factors that could cause our actual results, performance or achievements to differ materially from historical results



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or any future results, performance or achievements expressed, suggested or implied by such forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding our expectations for our lymph node targeted approach to treating cancer and infectious diseases, our expectation that the AMP platform can boost TCR-T cell therapy in the lymph nodes, our expectation to move from Cohort 2 to Cohort 3 in the AMPLIFY-201 study in the next quarter, into our Phase 1b/2 trial in early 2023, our expectation that the study of the ELI-002 and LIBTAYO® combination will begin upon the completion of Phase 1b studies of ELI-002 as a monotherapy, our hope that ELI-002's immune education in combination with LIBTAYO's ability to block PD-1 and activate the ELI-002-induced T cells to target cancers will provide a new treatment option for patients living with these difficult to treat cancers, our expectation that initial safety, dose escalation, and correlative biomarker data from the Phase 1 portion of the trial will be available by the first half of 2022, our ability to share data from the AMPLIFY-201 study in the coming months, the ability of our proprietary AMP platform to deliver ELI-002 directly to the lymph nodes and our belief that it may stimulate an enhanced immune response and the general ability and potential of our proprietary Amphiphile, or AMP, platform, to deliver investigational immunotherapeutics directly to the lymph nodes and our expectation regarding biomarkers ability to detect persistent circulating tumor DNA. Applicable risks and uncertainties that could cause our actual results, performance or achievements to differ materially from historical results or any future results, performance or achievements expressed, suggested or implied by our forward-looking statements include, among others: the potential that we experience slower than expected enrollment in our clinical trials, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; the results of our clinical trials do not continue to support our approach and expectation of lymph node targeting for the treatment enhance of cancer and infectious diseases or that the results do not continue to support that the AMP platform enhances TCR-T clinical responses in solid tumors; our limited operating history and historical losses; our need to raise capital to fund our research and development programs; the early stage nature of the development of our product candidates; our ability to obtain orphan drug designation from the FDA; competition from various competitors in the markets targeted by our product candidates, including from competitors with substantially greater resources than us; our general dependence on third parties in connection with manufacturing, clinical trials and preclinical studies; the potential complexity of the manufacturing process for our product candidates; our ability to protect our intellectual property; our dependence on the patents we license from the Massachusetts Institute of Technology, or MIT; our compliance with healthcare laws and regulations; and risks relating to the impact on of COVID-19 or other infectious diseases on our business. The forward-looking statements contained in this press release reflect our current views with respect to future events, and we do not undertake and specifically disclaim any obligation to update any forward-looking statements, except as required by law.

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