Elicio Therapeutics Presents Updated Preliminary Immunogenicity Data from the Ongoing Phase 1 Study of ELI-002 and New Preclinical Data on ELI-007 and ELI-008 at the Society for Immunotherapy of Cancer (SITC 2023) Annual Meeting

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- *In patients with high relapse risk mKRAS-driven pancreatic and colorectal cancers who were given ELI-002 2P, an investigational therapeutic cancer vaccine, as monotherapy, 87% (20/23) had direct ex vivo mKRAS-specific T cell responses, and 100% (23/23) had in vitro stimulated responses. The strength of the induced T cell response correlated with a significantly reduced risk of relapse and death.*

- *Among the four patients assessed for durability of immune response post-boost immunizations with ELI-002, 100% maintained elevated T cell responses above baseline, with 75% producing an increased response post-boost.*

- *ELI-007, an investigational mutant BRAF-peptide vaccine, and ELI-008, an investigational p53 hotspot mutation-peptide vaccine, demonstrated strong induction of tumor-antigen-specific T cell responses in mice, increased >10-500-fold over conventional comparators.*

BOSTON, Nov. 03, 2023 (GLOBE NEWSWIRE) -- Elicio Therapeutics, Inc. (Nasdaq: ELTX, “Elicio Therapeutics” or “Elicio”), a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer, today announced promising updated preliminary translational data from the ongoing Phase 1 (AMPLIFY-201) study of its lead cancer vaccine candidate, ELI-002, in patients with high relapse risk mKRAS-driven pancreatic and colorectal cancers, and new preclinical data on vaccine candidates, ELI-007 and ELI-008.

The data will be presented at the Society for Immunotherapy of Cancer 38th Annual Meeting (SITC 2023) taking place at the San Diego Convention Center in San Diego, CA and virtually from November 1-5, 2023.

“The data presented here and at the AACR Special Conference on Pancreatic Cancer in September, demonstrate that the T cell-targeted mechanism of action of ELI-002 is induced in high relapse risk patients with pancreatic and colorectal cancers, with the strength of the antigen-specific immune responses induced by ELI-002 correlating with reduced relapse risk. This is an important validation of ELI-002 and the Amphiphile platform, which promise to harness the power of the lymph nodes to generate and activate T cells to target solid tumors,” said Christopher Haqq, M.D., Ph.D., Elicio’s Executive Vice President, Head of Research and Development, and Chief Medical Officer.

Pete DeMuth, Ph.D., Chief Scientific Officer, added, “These preclinical data demonstrate ELI-007 and ELI-008 induced strong T cell activation against both mutant p53 and BRAF representing a set of promising therapeutic opportunities for targeting a large fraction of human solid cancers. These data, showing T cell responses >10-500-fold increased over soluble peptide comparators, also suggest the broad applicability of our AMP platform and build on previous data supporting our lymph node-targeting approach for addressing some of the most aggressive cancers.”

Poster Presentation Summary:

Title: ELI-002 Immunotherapy Induces Broad Polyfunctional T Cell Responses in Subjects with High Relapse Risk KRAS Mutated Pancreatic Ductal Adenocarcinoma and Colorectal Cancer
Abstract Number: 656
Presenter: James Perry

ELI-002 2P is an investigational therapeutic cancer vaccine targeting solid tumors driven by G12D and G12R mutations in KRAS.

Study Overview

- ELI-002 2P consists of 2 Amph-modified mKRAS peptide antigens, Amph-G12D and Amph-G12R (Amph-Peptides 2P), and an Amph-modified immune-stimulatory oligonucleotide adjuvant (Amph-CpG-7909).
- ELI-002 2P was administered as an adjuvant treatment for patients with high relapse risk mutant KRAS pancreatic ductal adenocarcinoma (PDAC) and colorectal cancer (CRC).
- 25 subjects received ELI-002 2P at 1.4 mg of Amph-Peptides 2P and Amph-CpG-7909 at 5

escalating dose levels; 0.1, 0.5, 2.5, 5, and 10 mg. Peripheral blood was collected longitudinally to assess the specificity, polyfunctionality and phenotype of mKRAS-specific T cells.

Preliminary Study Findings including immune response durability (as of April 25, 2023 Data Cut-Off Date)

- Direct *ex vivo* mKRAS-specific T cell responses were observed in 20/23 patients (87%), and *in vitro* stimulated responses were observed in 23/23 patients (100%); a 100% (9/9) *ex vivo* response rate was observed at the highest administered doses of ELI-002.
- 90% of immune responders had T cell responses to ≥ two mKRAS antigens, with 35% responding to all seven mKRAS antigens evaluated. 50% of patients had mKRAS-specific T cell responses in both CD4 and CD8 T cell subsets.
- Vaccine-induced mKRAS-specific T cells were characterized by polyfunctional effector cytokine response (IFNγ, TNFα), cytolytic function (Granzyme B), activation (CD137), proliferation (Ki67) and memory phenotype among other markers of functional quality.
- Four patients were assessed for durability of immune response post-boost immunizations, and 100% (4/4) of evaluable patients maintained T cell responses above baseline, with 75% (3/4) producing further increases post-boost.
- Patients with *ex vivo* T cell responses ≥ the median fold-change over baseline for all evaluable patients (13-fold) demonstrated a significantly improved decrease in tumor biomarkers. The strength of T cell responses correlated with an 86% reduced risk of relapse (RFS) and death.

Title: Lymph node targeted AMP-peptide vaccines generate functional T cell immunity against mutant p53 and BRAF
Abstract Number: 1145
Presenter: Martin Steinbuck, Ph.D.

ELI-007, a mutant BRAF-peptide vaccine, and ELI-008, a p53 hotspot mutation-peptide vaccine, are being evaluated in studies funded by a grant from the Gastro-Intestinal (GI) Research Foundation with the aim of developing multivalent cancer vaccines targeting several mutations.

Study Overview

- ELI-007 is comprised of the V600E and V600K mutant antigens, targeting BRAF-driven cancers. ELI-008 is a combination of several mutant p53 tumor suppressor peptides.
- C57BL/6J mice were immunized with three doses of AMP-modified or soluble comparator vaccines, comprised of either mBRAF or mp53 peptides, and CpG-adjuvant, which were subcutaneously injected in two-week intervals.
- Immunological readouts were performed seven days post dosing. To assess antigen-specific T cell responses, ELISpot/Fluorospot (IFNγ, TNFα, IL-2, Granzyme B), multiplexed proteomic, and flow cytometric analysis of effector cytokines (IFNγ, TNFα) were performed in various tissues following antigenic stimulation.
- Cytolytic capabilities of antigen-specific T cells were evaluated in *in vivo* killing assays, in which fluorescently labeled, antigen-pulsed cells from naïve donor mice were intravenously transferred to immunized recipient mice, recovered after 24 hours from spleens, and analyzed by flow cytometry.

New Study Findings

- Both ELI-007 and ELI-008 have demonstrated strong induction of tumor-antigen-specific T cell responses in mice.
    - Lymph node targeted AMP-vaccination resulted in T cell responses >10-500-fold increased over conventional comparators.
    - Induced T cells were polyfunctional exhibiting production of multiple effector cytokines (IFNγ, TNFα, IL-2) and demonstrating cytotoxic killing *in vivo* alongside enhanced production of Granzyme B.

- ELI-007 and ELI-008 have the potential to address the high unmet medical need for millions of patients diagnosed with BRAF and p53 mutated cancers annually.

About ELI-002
ELI-002 is a structurally novel investigational AMP therapeutic immunotherapy targeting mutant KRAS-driven cancers. KRAS mutations are among the most prevalent human cancers. The seven KRAS driver mutations targeted by the ELI-002 7P formulation are present in 25% of all solid tumors. In particular, 93% of pancreatic ductal adenocarcinoma and 52% of colorectal cancers, those most prevalent in the AMPLIFY-201 study, are positive for KRAS mutations. In addition, 27% of non-small cell lung cancers are positive for KRAS mutations. 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 2P is currently being studied in a Phase 1 trial (AMPLIFY-201) in patients with high relapse risk mKRAS-driven solid tumors, following surgery and chemotherapy (**NCT04853017**). ELI-002 7P, is currently being studied in AMPLIFY-7P, a Phase 1/2 trial in patients with high relapse risk mKRAS-driven solid tumors (**NCT05726864**). The ELI-002 7P formulation is designed to provide immune response coverage against seven of the most common 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 based upon preclinical studies.

Our AMP platform, originally developed at the Massachusetts Institute of Technology has broad potential in the cancer space 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 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. By combining expertise in immunology and immunotherapy, Elicio is engineering investigational Amphiphile (AMP) immunotherapies 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.

Cautionary Note on Forward-Looking Statements
Certain statements contained in this communication regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding Elicio’s planned clinical programs, including planned clinical trials, the potential of Elicio’s product candidates, the expected participation and presentation at upcoming conferences, and other statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Elicio undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, Elicio’s plans to develop and commercialize its product candidates, including ELI-002; the timing of the availability of data from Elicio’s clinical trials; Elicio’s plans to research, develop and commercialize its current and future product candidates; Elicio’s ability to enter into new collaborations, in-licensing arrangements or partnerships, and to fulfill its obligations under any such agreements; the clinical utility, potential benefits and market acceptance of Elicio’s product candidates; Elicio’s commercialization, marketing and manufacturing capabilities and strategy; Elicio’s ability to identify additional products or product candidates with significant commercial potential; and developments and projections relating to Elicio’s competitors and our industry.

New factors emerge from time to time, and it is not possible for us to predict all such factors, nor can we assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These risks are more fully discussed in the current report on Form 8-K that was filed with the SEC on June 2, 2023, and Elicio’s periodic reports and other documents filed from time to time with the SEC. Forward-looking statements included in this release are based on information available to Elicio as of the date of this release. Elicio does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this release, except to the extent required by law.

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