Alpine Immune Sciences Announces First Subjects Dosed in Phase I Clinical Trial for Lead Autoimmune/Inflammatory Disease Program ALPN-101

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First Dual ICOS/CD28 Inhibitor to Enter Clinical Trials

SEATTLE--(BUSINESS WIRE)--Feb. 11, 2019-- Alpine Immune Sciences, Inc. (NASDAQ:ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer, autoimmune/inflammatory, and other diseases, today announced successful initiation of dosing in its first-in-human Phase I study of ALPN-101, a first-in-class dual ICOS/CD28 antagonist.

This study will evaluate the safety and tolerability of single- and multiple-ascending intravenous and/or subcutaneous doses of ALPN-101. In addition, pharmacokinetics, pharmacodynamics, and exploratory biomarkers are being evaluated to help determine ALPN-101's potential for the treatment of autoimmune and inflammatory diseases. The company expects data later in 2019.

"This first dosing in the initial clinical trial of ALPN-101 is an important milestone for Alpine as we have now transitioned to a clinical-stage development company," stated Mitchell H. Gold, MD, Executive Chairman and Chief Executive Officer of Alpine. "We look forward to further exploring how our first-in-class dual ICOS/CD28 antagonist will potentially improve outcomes of patients suffering from debilitating autoimmune and inflammatory diseases such as GvHD and psoriatic arthritis."

AIS-A01 is a randomized, placebo-controlled, blinded study in adult healthy volunteers to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics of single and multiple ascending doses of ALPN-101. The trial is being conducted in Australia. More information is available at www.clinicaltrials.gov (Identifier: NCT03748836).

About ALPN-101

ALPN-101 is a novel Fc fusion protein of a human inducible T cell costimulator ligand (ICOSL) variant immunoglobulin domain (vIgD™), and a first-in-class therapeutic simultaneously inhibiting the CD28 and ICOS inflammation pathways. CD28 and ICOS are closely related costimulatory molecules with partially overlapping roles in T cell activation likely connected to multiple autoimmune and inflammatory diseases. In preclinical models of graft versus host disease, inflammatory arthritis, and multiple sclerosis, ALPN-101 demonstrates efficacy superior to blockade of the CD28 or ICOS pathways alone.

ALPN-101 was engineered using Alpine's vIgD platform, which uses directed evolution to transform native IgSF proteins into multifunctional protein therapeutics.

About Alpine Immune Sciences, Inc.

Alpine Immune Sciences, Inc. is committed to leading a new wave of functional immune therapeutics. Alpine is employing directed evolution to create potentially powerful multifunctional immunotherapies to improve patients' lives. Alpine has two lead programs. The first, ALPN-101 for autoimmune/inflammatory diseases, is a dual ICOS/CD28 antagonist, engineered to reduce pathogenic immune responses. The second, ALPN-202 for cancer, is a dual PD-L1/CTLA-4 antagonist and PD-L1-dependent CD28 costimulator intended to combine checkpoint inhibition with T cell costimulation – an approach currently absent from approved checkpoint therapies. Alpine is backed by world-class research and development capabilities, a highly-productive scientific platform, and a proven management team. For more information, visit www.alpineimmunesciences.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements are not based on historical fact and include statements regarding our platform technology and potential therapies, the timing of and results from clinical trials and pre-clinical development activities, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of our product candidates, the efficacy of our clinical trial designs and our ability to successfully develop and achieve milestones in our development programs. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "intend," and other similar expressions among others. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our product candidates; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; our discovery-stage and pre-clinical programs may not advance into the clinic or result in approved products; any of our product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; the impact of competition; adverse conditions in the general domestic and global economic markets; as well as the other risks identified in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and we undertake no obligation to update forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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