Alpine Immune Sciences Announces First Patient Dosed in NEON-1 Phase 1 Trial of ALPN-202 in Patients with Advanced Malignancies

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- ALPN-202 is a first-in-class conditional CD28 costimulator and dual checkpoint inhibitor -

SEATTLE--(BUSINESS WIRE)--Jun. 24, 2020-- Alpine Immune Sciences, Inc. (NASDAQ:ALPN), a leading clinical-stage immunotherapy company focused on developing innovative treatments for cancer and autoimmune/inflammatory diseases, today announced that the first patient has been successfully dosed in its NEON-1 Phase 1 study of ALPN-202, a first-in-class conditional CD28 costimulator and dual checkpoint inhibitor, in patients with advanced malignancies.

"This is a particularly exciting milestone," said Mitchell Gold, MD, Alpine's Chairman and CEO, "because ALPN-202 embodies the unique founding concepts of Alpine's vIgD platform, incorporating tri-functional agonism and antagonism in a single proprietary functional domain. As we continue with the study, ALPN-202 will hopefully help establish the clinical relevance of localized CD28 costimulation to checkpoint inhibition in cancer."

NEON-1 includes two parts: dose escalation and expansion cohort(s). It will enroll adults with advanced solid tumors or lymphoma refractory or resistant to standard therapy, including checkpoint inhibitors when indicated. Measurable disease is required for most participants, as are an ECOG status of 0 to 2 and adequate hematological, renal, and hepatic function. Dose escalation begins with single-participant cohorts to minimize the number of participants anticipated to receive subtherapeutic doses, followed by standard 3 + 3 cohorts where two dose regimens, weekly versus every three weeks, will be studied in parallel. Expansion cohorts will explore specific tumor types and/or biomarker-selected tumors, based upon the experience during dose escalation. Safety endpoints include dose-limiting toxicities, adverse events, and circulating cytokines. Objective responses will be assessed by RECIST v1.1 for solid tumors and Lugano criteria for lymphoma. Pharmacokinetics and pharmacodynamics will also be evaluated. More information is available at www.clinicaltrials.gov (NCT04186637).

About ALPN-202

ALPN-202 is a first-in-class, conditional CD28 costimulator and dual checkpoint inhibitor designed to improve upon the efficacy of combined checkpoint inhibition while limiting significant toxicities. Preclinical studies of ALPN-202 have demonstrated superior efficacy in tumor models compared to checkpoint inhibition alone. NEON-1 (NCT04186637), a Phase 1 study of ALPN-202 in patients with advanced malignancies, is currently enrolling.

About Alpine Immune Sciences, Inc.

Alpine Immune Sciences, Inc. is committed to leading a new wave of immune therapeutics, creating potentially powerful multifunctional immunotherapies to improve patients' lives via unique protein engineering technologies. 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. Follow @AlpineImmuneSci on Twitter and LinkedIn.

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, clinical and regulatory objectives and the timing thereof, 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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