Neoleukin Therapeutics Announces Initiation of Phase 1 NL-201 Trial

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– Trial Evaluating NL-201 in Patients with Advanced Solid Tumors Underway –

SEATTLE, May 05, 2021 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced dosing the first patient in a Phase 1 trial of NL-201 for advanced solid tumors. NL-201 is a *de novo* protein designed to mimic the therapeutic activity of natural cytokines IL-2 and IL-15. The Phase 1 study will be conducted at multiple sites in Australia and North America. The first patient was dosed in Australia.

The Phase 1 study is planned to enroll up to 120 patients with advanced, relapsed, or refractory solid tumors. Patients will receive monotherapy, intravenous NL-201 and may continue treatment until disease progression. The trial will assess safety, pharmacokinetics, pharmacodynamics, immunogenicity, and antitumor activity. When the recommended dose and schedule are determined, Neoleukin expects to enroll indication-specific expansion cohorts of patients with renal cell carcinoma and melanoma.

"NL-201 is a novel immunotherapy that was computationally designed to overcome the limitations of native IL-2 by eliminating the alpha receptor binding interface. We believe it is the first fully de novo protein to enter clinical development,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “Our preclinical studies have demonstrated activation of immune cells at low doses, potentially reducing the toxicities associated with high-dose IL-2. We are excited to begin this trial to determine the optimal dose and schedule for NL-201 and evaluate its potential as a monotherapy to help cancer patients.”

About NL-201

NL-201 is a *de novo* receptor agonist of the IL-2 and IL-15 receptors, designed to expand cancer-fighting CD8 T cells and natural killer (NK) cells without any bias toward cells expressing the alpha receptor subunit (CD25). Previously presented preclinical data has demonstrated the ability of NL-201 to stimulate and expand CD8+ and NK cells at low doses with minimal impact on immunosuppressive regulatory T cells. Furthermore, NL-201 has demonstrated both monotherapy and combination activity across a wide range of preclinical syngeneic tumor models.

About Neoleukin Therapeutics, Inc.

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. Neoleukin’s lead product candidate, NL-201, is a combined IL-2 and IL-15 agonist designed to improve tolerability and activity by eliminating the alpha receptor binding interface. For more information, please visit the Neoleukin website: www.neoleukin.com.

Safe Harbor / Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the therapeutic properties and potential of the company’s *de novo* protein design technology, the results of the clinical trial for NL-201, and planned clinical and development activities and timelines. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to the company’s cash forecasts, the company’s ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the timing and results of preclinical and clinical trials, the timing of announcements and updates relating to the company’s clinical trials, and related data market conditions and further impacts of COVID-19, that could cause actual results to differ materially from what Neoleukin expects. Further information on potential risk factors that could affect Neoleukin’s business and its financial results are detailed under the heading “Risk Factors” in documents the company files from time to time with the Securities and Exchange Commission (SEC), and other reports as filed with the SEC. Neoleukin undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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