Neoleukin Therapeutics Announces Clearance to Proceed with NL-201 Phase 1 Clinical Trial in the United States

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SEATTLE, April 26, 2021 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has removed the clinical hold related to its Investigational New Drug (IND) Application to begin a Phase 1 clinical program of its immunotherapeutic candidate, NL-201.

Neoleukin previously announced on January 8, 2021 that it received a clinical hold letter from the FDA requesting development of a new assay that more precisely measures the amount of protein being administered and demonstration of accurate delivery of the intended dose of NL-201.

“We are pleased to have addressed the FDA’s concerns and receive clearance to proceed with our Phase 1 trial of NL-201 in the U.S.,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “We believe NL-201 represents the first *de novo* protein therapeutic to enter clinical development and look forward to evaluating its safety and preliminary antitumor activity in patients with advanced solid tumors.”

The Phase 1 study will evaluate monotherapy, intravenous treatment with NL-201 in up to 120 patients with advanced, relapsed or refractory solid tumors. The trial will assess safety, pharmacokinetics, immunogenicity, pharmacodynamics, and antitumor activity. When the recommended dose and schedule are determined, indication-specific expansion cohorts will be enrolled to estimate safety and antitumor activity. The trial is planned to be conducted in North America and Australia. Recruitment activities have recently begun in Australia. Additional sites in North America are expected to begin recruitment over the next several months.

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 have 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.

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 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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