Neoleukin Therapeutics Announces Submission of Investigational New Drug Application for NL-201 De Novo Protein Immunotherapy Candidate for Cancer

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SEATTLE, Dec. 10, 2020 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design de novo protein therapeutics, today announced the submission of an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration to begin a Phase 1 clinical program of its lead immunotherapeutic candidate, NL-201. NL-201 is a computationally designed *de novo* protein that is a mimetic of natural cytokines IL-2 and IL-15.

“This IND submission is an important milestone for our company, and I’m proud of our team’s efforts in advancing NL-201 toward first-in-human evaluation,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “We look forward to initiating patient enrollment in our Phase 1 trial, which is planned to be conducted in both North America and Australia.”

The Phase 1 study is expected to enroll up to 120 patients with relapsed or refractory solid tumors. Patients will receive intravenous monotherapy with NL-201 in order to assess safety, pharmacokinetics, 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. In addition to the IND application, Neoleukin has submitted a Clinical Trial Notification (CTN) application for NL-201 in Australia.

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, planned development activities and timelines and the therapeutic properties and potential of the company’s product candidates and *de novo* protein design technology. 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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