Neoleukin Therapeutics Receives Clinical Hold Letter from U.S. FDA Related to CMC Assay Development for NL-201

January 8, 2021

SEATTLE, Jan. 08, 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 on January 7, 2021, it received a clinical hold letter from the U.S. Food and Drug Administration (FDA) related to its Investigational New Drug (IND) Application to begin a Phase 1 clinical program of its immunotherapeutic candidate, NL-201.

The FDA has informed Neoleukin that it needs to develop a new assay that more precisely measures the amount of protein being administered and demonstrate with this assay that dose and administration procedures will accurately deliver the intended dose of NL-201. The FDA also had additional requests not related to the clinical hold to be addressed by amendment of the IND.

“We will work diligently to address the FDA’s questions as quickly as possible,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “We believe that we will be able to develop the requested assay and respond within the next several months. While we do not have a definitive timeline as to when we will be able to obtain clearance to proceed, we look forward to working with the FDA to satisfy their requests.”

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, regulatory submissions and approval 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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