Neoleukin Therapeutics Announces Year End 2021 Financial Results and Corporate Update

March 1, 2022

- Interim data from NL-201 Phase 1 trial for patients with relapsed and refractory solid tumors anticipated in the second half of 2022 –

- $142.5 million in cash and cash equivalents expected to provide runway into the second half of 2023 –

- Appointment of Rohan Palekar to Board of Directors –

- Company to host conference call today, March 1, 2022 at 1:30 p.m. PT / 4:30 p.m. ET –

SEATTLE, March 01, 2022 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced financial results and a corporate update for the year ended December 31, 2021.

“We’ve made significant strides in 2021 that will drive our efforts in 2022, including the start of clinical development for NL-201, the generation of preclinical findings supporting NL-201’s activity in different indications and combinations, and highlighting new avenues for *de novo* protein design candidates and potential applications to expand our development pipeline,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “In 2022, we look forward to reporting interim data from our Phase 1 trial of NL-201, beginning a combination trial of NL-201 with pembrolizumab, initiating a Phase 1 trial of NL-201 in hematologic malignancies and continuing to pursue exciting avenues for additional *de novo* protein candidates.”

NL-201 Clinical Development Update

NL-201 is a computationally designed *de novo* protein that is a mimetic of natural cytokines IL-2 and IL-15 designed to expand cancer-fighting CD8 T cells and natural killer (NK) cells without a bias toward cells expressing the IL-2 receptor alpha subunit (CD25). NL-201 is currently in a Phase 1 clinical trial for patients with relapsed and refractory solid tumors to assess safety, pharmacokinetics, pharmacodynamics, immunogenicity, and antitumor activity.

The open label Phase 1 trial of NL-201 is active at participating sites in the United States, Australia and Canada. Enrollment in the trial is progressing. Dose escalation is currently underway and will continue through 2022. Interim data is expected to be reported in the second half of 2022.

In January 2022, Neoleukin announced a clinical trial collaboration and supply agreement with Merck (known as MSD outside the United States and Canada). The agreement will allow for the evaluation of safety and efficacy of Neoleukin’s NL-201 in combination with Merck’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in an ongoing Phase 1 trial. Neoleukin will evaluate NL-201 plus pembrolizumab as part of the company’s ongoing Phase 1 trial in patients with advanced, relapsed or refractory solid tumors. Up to 132 patients will be enrolled in the combination arm of the study. The trial is assessing safety, pharmacokinetics, pharmacodynamics, immunogenicity, and antitumor activity.

In December 2021, Neoleukin announced the presentation of preclinical data on NL-201 in multiple myeloma at the 63RD American Society of Hematology (ASH) Annual Meeting and Exposition. Additionally, a published abstract in Blood reported on NL-201 antitumor activity in preclinical studies of non-Hodgkin lymphoma. The preclinical multiple myeloma data, demonstrate the ability of NL-201 to prevent relapse in murine myeloma models following autologous stem cell transplant. Experimental results indicate that anti-myeloma activity is mediated by expansion of cytotoxic memory CD8 T cells and a decrease in T-regulatory CD4 cells in the bone marrow. Furthermore, NL-201 treated mice had an increase in bone marrow T-cells expressing granzyme B and a decrease in the T-cell exhaustion phenotype. Neoleukin believes that these findings support the further evaluation of NL-201 in hematologic malignancies.

In November 2021, Neoleukin announced the presentation of four abstracts highlighting new preclinical data on NL-201 at the Society for Immunotherapy of Cancer’s 36 TH Annual Meeting (SITC 2021). The presentation highlighted preclinical data on NL-201 alone and in several combination regimens. New data demonstrated that NL-201 can activate the tumor microenvironment and increase T-cell receptor diversity in preclinical models. Findings also indicated that local, intratumoral administration of NL-201 can control both the injected and distant tumors with improved tolerability compared to systemic administration in preclinical models.

Board of Directors Transition

Neoleukin today announced the appointment of Rohan Palekar, Chief Executive Officer of 89bio, Inc. (NASDAQ:ETNB), to Neoleukin's Board of Directors, and the departure of Lewis "Rusty" Williams, MD, PhD, from the board. Mr. Palekar's career in the biopharmaceuticals industry spans more than 30 years, and he brings extensive strategic and operational experience spanning commercial and research and development functions.

Mr. Palekar has served as the CEO of 89bio since June 2018. Prior to that, Mr. Palekar served as President and CEO of Avanir Pharmaceuticals after a series of leadership roles in commercial and operations. Prior to Avanir, Mr. Palekar served as the Chief Commercial Officer of Medivation. Earlier in his career, Mr. Palekar spent 16 years at Johnson & Johnson in various senior commercial and strategic management roles including worldwide VP of Immunology. Mr. Palekar holds an MBA from the Amos Tuck School of Business Administration at Dartmouth College, a Chartered Accountant certification, and degrees in law and accounting from the University of Bombay.

Other Discovery Stage Efforts

In November 2021, Neoleukin delivered an oral presentation at the American College of Rheumatology Annual highlighting development of a potent and hyperstable computationally designed protein, Neo-5171, that blocks signaling by endogenous IL-2 and IL-15 with potential applications in inflammatory and autoimmune disorders. Neo-5171 is currently in the discovery development stage.

In addition to Neo-5171, Neoleukin's discovery stage pipeline includes a Treg agonist targeting autoimmune and inflammatory conditions and a next-generation IL-2 / IL-15 agonist for oncology indications.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $142.5 million as of December 31, 2021, compared to $192.6 million as of December 31, 2020.

Based upon current internal infrastructure and pipeline initiatives, Neoleukin believes it has sufficient cash to fund operations into the second half of 2023.

R&D Expenses: Research and development expenses for the year ended 2021 increased to $39.2 million from $24.3 million for the year ended 2020. The increase was primarily due to increased expenses incurred from clinical trial activities related to Neoleukin's lead product candidate, NL-201, personnel-related costs, and in connection with the advancement of other Neoleukin technologies. The increase was also due to facility-related costs associated with the build-out of Neoleukin's new headquarters and laboratory in Seattle, Washington.

G&A Expenses: General and administrative expenses for the year ended 2021 increased to $21.5 million from $17.2 million for the year ended 2020. The increase was primarily due to increases in personnel-related costs.

Gain on Sale of Aquinox Canada: The gain in the year ended 2020 relates to the sale of Aquinox Canada, a wholly owned subsidiary of Neoleukin. The gain of $7.8 million recognized was the total consideration of $8.2 million, less transaction costs of $0.4 million.

Net Loss: Net loss for the year ended 2021 was $60.7 million compared to a net loss of $33.3 million for the year ended 2020.

Conference Call Information

Neoleukin will host a conference call today to discuss 2021 financial results and provide a corporate update. Details as follows:

Date: March 1, 2022

Time: 1:30 p.m. Pacific / 4:30 p.m. Eastern

Toll-free: (866) 357-7878

International: (315) 625-3088

Conference ID: 8928189

Webcast URL: http://investor.neoleukin.com/events

The archived audio webcast will be available on the Investor Relations section of the Neoleukin website approximately two hours after the event and will be available for replay for at least 30 days after the event.

About NL-201

NL-201 is a de novo 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, expectations regarding cash forecasts, 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.

*KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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NEOLEUKIN THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data
(In thousands of U.S. dollars)

	December 31 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 142,467	$ 192,556
Other current assets	1,522	1,966
Non-current assets	19,274	15,997
Total assets	$ 163,263	$ 210,519
Liabilities		
Current liabilities	$ 8,636	$ 7,889
Non-current liabilities	11,763	11,414
Total liabilities	20,399	19,303
Stockholders' equity	142,864	191,216
Total liabilities and stockholders' equity	$ 163,263	$ 210,519

NEOLEUKIN THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations
(In thousands of U.S. dollars, except per share and share amounts)

	Year ended December 31, 2021	Year ended December 31, 2020
Operating loss		
Research and development	$ 39,162	$ 24,344
General and administrative	21,536	17,210
Gain on sale of Aquinox Canada	—	(7,826)
Total operating loss	60,698	33,728
Other income, net	6	451
Net loss	$ (60,692)	$ (33,277)
Net loss per common stock – basic and diluted	$ (1.10)	$ (0.64)
Basic and diluted weighted average common shares outstanding	55,041,662	51,825,022

Source: Neoleukin Therapeutics, Inc.