Neoleukin Therapeutics Announces Year End 2020 Financial Results

March 25, 2021

- Anticipating first patient for NL-201 Phase 1 Trial in 1H21 -

- Cash and cash equivalents of $192.6 million expected to fund operations into 2023 -

- Company to host Conference Call Today, March 25, 2021 at 1:30 p.m. Pacific / 4:30 p.m. Eastern -

SEATTLE, March 25, 2021 (GLOBE NEWSWIRE) -- Neoleukin Therapeutics, Inc., “Neoleukin” (NASDAQ:NLTX), a biopharmaceutical company utilizing sophisticated computational methods to design *de novo* protein therapeutics, today announced a corporate update and financial results for the year ended December 31, 2020.

“Despite the challenges of the COVID-19 pandemic, our team has remained focused and committed to the advancement of our *de novo* technology platform, paving the way for future achievements this year and beyond,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “In 2021, we look forward to advancing our first-in-human trials of NL-201 and expanding our *de novo* protein technology and pipeline.”

Recent Updates

NL-201 Development

NL-201 is a computationally designed *de novo* protein that is a mimetic of natural cytokines IL-2 and IL-15. In the fourth quarter of 2020, Neoleukin submitted a Clinical Trial Notification ("CTN") for Phase 1 clinical testing of NL-201 in Australia, which is anticipated to be initiated at leading clinical research centers in the first half of 2021. In addition, in December 2020, Neoleukin announced submission of an Investigational New Drug ("IND") Application with the U.S. Food and Drug Administration ("FDA") to begin Phase 1 clinical testing of NL-201 in the U.S. The planned clinical trial of NL-201 in Australia and North America is expected to enroll patients with relapsed or refractory solid tumors. Patients will receive NL-201 as intravenous monotherapy to assess safety, pharmacokinetics, pharmacodynamics, and antitumor activity.

On January 7, 2021, Neoleukin received a clinical hold letter from the FDA related to its IND Application. The FDA requested that the company develop a new assay for methods-of-use testing and to demonstrate that this assay can more precisely measure the amount of NL-201 that is delivered to the patient when following the pharmacy preparation and administration instructions. The FDA also had additional requests not related to the clinical hold to be addressed by amendment of the IND. Neoleukin is working to address the FDA’s questions as quickly as possible and currently expects to resolve the clinical hold as well as to begin enrollment of patients in the first half of 2021.

In addition to the systemic trial, Neoleukin is planning a trial of NL-201 to test local administration in order to achieve higher drug concentrations in the tumor microenvironment. The company expects the local administration trial to begin by the end of 2021 and will provide further details as appropriate.

In November 2020, Neoleukin presented preclinical data on NL-201 at the Society for Immunotherapy of Cancer’s 35 TH Anniversary Annual Meeting. These data highlighted the results of multiple experiments of NL-201 in combination with immunotherapies and demonstrate that NL-201 enhances activity of checkpoint inhibitors and tumor-targeting antibodies in preclinical models.

***De Novo* Protein Design for Coronavirus – NL-CVX1**

In November 2020, Neoleukin announced publication in the journal Science of a manuscript describing novel molecules designed to treat or prevent infection by SARS-CoV-2, the virus that causes COVID-19. As reported, the optimized proteins act as decoys that bind to the SARS-CoV-2 spike protein with high affinity, preventing its association with the viral receptor hACE2 and blocking cellular entry. The lead molecule, NL-CVX1 (CTC-445.2d), was shown to prevent infection of multiple cell lines in vitro and, when administered intranasally, to prevent serious consequences of SARS-CoV-2 infection in hamsters. The rapid development of this targeted protein demonstrates the potential of the Neoleukin *de novo* protein design platform. Neoleukin is currently planning a first-in-human trial of NL-CVX1, and will continue to evaluate the program as the SARS-CoV-2 landscape evolves.

Other Research Updates

Neoleukin has multiple research projects underway evaluating the applications of *de novo* protein technology to develop agonists and antagonists of immune pathways. This includes development of potent and hyperstable inhibitors of inflammation that could be used to treat autoimmune conditions. Neoleukin currently plans to announce additional information about its pipeline program during the second half of 2021.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $192.6 million as of December 31, 2020, compared to $143.1 million as of December 31, 2019. The increase was primarily driven by the completion of a public offering in July 2020 for net proceeds of $71.3 million. Based upon current internal infrastructure and pipeline initiatives, Neoleukin believes it has sufficient cash to fund operations into 2023.

R&D Expenses: Research and development expenses for the year ended December 31, 2020 were $24.3 million compared to $4.4 million for the year ended December 31, 2019. The increase in research and development expenses during the year ended December 31, 2020 was due to increased expenses incurred from IND-enabling activities related to our lead product candidate, NL-201, and in connection with the advancement of other Neoleukin technologies. Lower research and development costs during the year ended December 31, 2019 reflect the fact that prior to the merger between Aquinox Pharmaceuticals, Inc. ("Aquinox") and Neoleukin Therapeutics, Inc. ("Former Neoleukin") in August, 2019, all research and development activities with rosiptor had been suspended since June 2018.

G&A Expenses: General and administrative expenses for the year ended December 31, 2020 were $17.2 million compared to $18.8 million for the year ended December 31, 2019. The higher general and administrative expenses for the year ended December 31, 2019 as compared to the year ended December 31, 2020 were primarily due to severance costs and the recognition of stock-based compensation expense for certain options that vested as a result of the merger between Aquinox and Former Neoleukin in August 2019. The general and administrative expenses for the year ended December 31, 2020 reflect an increase in personnel related costs, facility-related costs, and professional service fees.

Acquired in-process R&D: The acquired in-process research and development expense of $47.7 million in 2019 arose from the merger between Aquinox and Former Neoleukin in 2019 and was expensed immediately in accordance with accounting standards.

Gain on Sale of Aquinox Canada: The gain relates to the sale of Aquinox Canada, a wholly owned subsidiary of the company, during the three months ended September 30, 2020. The gain of $7.8 million recognized is the total consideration of $8.2 million, less transaction costs of $0.4 million.

Net Loss: Net loss for the year ended December 31, 2020 was $33.3 million compared to a net loss of $69.4 million for the year ended December 31, 2019. The higher net loss in 2019 is primarily due to the acquired in-process research and development expense from the merger.

Conference Call Information

Neoleukin will host a conference call today to discuss 2020 financial results and provide a corporate update. Details as follows:

Date: March 25, 2021
Time: 1:30 p.m. Pacific / 4:30 p.m. Eastern
Toll-free: (866) 357-7878
International: (315) 625-3088
Conference ID: 2666855
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* 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, including risks related to the current FDA hold on NL-201, 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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NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated balance sheet data
(In thousands of U.S. dollars)

	December 31, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 192,556	$ 143,093
Other current assets	1,966	503
Non-current assets	15,997	3,427
Total assets	$ 210,519	$ 147,023
Liabilities		
Current liabilities	$ 7,889	$ 4,743
Non-current liabilities	11,414	593
Total liabilities	19,303	5,336
Stockholders' equity	191,216	141,687
Total liabilities and stockholders' equity	$ 210,519	$ 147,023

NEOLEUKIN THERAPEUTICS, INC.

Condensed consolidated statement of operations
(In thousands of U.S. dollars, except per share and share amounts)

	Year ended December 31, 2020	Year ended December 31, 2019
Operating loss		
Research and development	$ 24,344	$ 4,417
Acquired in-process research and development	—	47,716
General and administrative	17,210	18,826
Gain on sale of Aquinox Canada	(7,826)	—
Total operating loss	33,728	70,959
Other income, net	451	1,517
Net loss	33,277	69,442
Net loss per common stock - basic and diluted	$ (0.64)	$ (2.57)
Basic and diluted weighted average common shares outstanding	51,825,022	27,030,355

neoleukin™ THERAPEUTICS

Source: Neoleukin Therapeutics, Inc.