Neoleukin Therapeutics Announces Third Quarter 2020 Financial Results and Corporate Update

November 9, 2020

-NL-201 IND submission anticipated by year end 2020-

-Clinical Trial Notification application submitted in Australia-

-Ended 3rd quarter with $201.2 million in cash and cash equivalents-

SEATTLE, Nov. 09, 2020 (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 third quarter ended September 30, 2020.

“The past quarter has been highly productive at Neoleukin as we continue to advance NL-201 toward an IND and prepare to initiate our first clinical trial in patients with advanced cancer,” said Jonathan Drachman, M.D., Chief Executive Officer of Neoleukin. “This represents an important step for Neoleukin and for the field of *de novo* protein design. In addition, we recently disclosed details about NL-CVX1, a *de novo* protein designed to bind the spike protein of SARS-CoV-2 and to block viral infection of mammalian cells. These data, published in the journal Science, demonstrate the broad applicability and speed of our *de novo* design platform to address serious biological problems.”

Recent Updates

NL-201 – IND on Track, CTN Application Submission in Australia

Neoleukin remains focused on its efforts to submit an Investigational New Drug (IND) application for its lead immunotherapy therapeutic candidate, NL-201, an IL-2 and IL-15 agonist, during the fourth quarter of 2020. At this time, Neoleukin does not expect a delay in the submission of its IND due to COVID-19 but acknowledges the potential exists for this timing to be impacted. In addition, the company has submitted a Clinical Trial Notification (CTN) application for NL-201 in Australia. The planned first-in-human clinical trials for NL-201 will test intravenous, monotherapy in patients with advanced solid tumors to determine the safety and tolerability of various dosing regimens.

De Novo Protein Design for Coronavirus – NL-CVX1

In November 2020, Neoleukin announced the publication of its scientific work in the journal *Science* describing the creation of novel molecules designed to treat or prevent infection by SARS-CoV-2, the virus that causes COVID-19. As reported, the optimized, hyperstable 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 human cell lines *in vitro* and to protect hamsters from serious consequences of SARS-CoV-2 infection when administered intranasally. Neoleukin is currently evaluating the possibility of advancing this molecule to clinical trials in humans.

These results demonstrate the potential of Neoleukin’s computational protein design platform and its scientific team to rapidly engineer *de novo* proteins that could potentially address a variety of biological problems.

Executive & Board Appointments

In September 2020, Neoleukin announced the appointment of Martin Babler, President and Chief Executive Officer of Principia Biopharma, Inc. (NASDAQ: PRNB), to the company’s Board of Directors. Mr. Babler brings decades of experience in business and commercial development, marketing and leadership in the biopharmaceutical industry.

In October 2020, Neoleukin announced the appointment of Holly K. Vance as General Counsel. Ms. Vance joins Neoleukin from the Bill & Melinda Gates Foundation, where she served as Associate General Counsel, working with the foundation’s Strategic Investment Fund with a focus in the life sciences sector. She previously served as partner in the Seattle office of the global law firm K&L Gates LLP.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $201.2 million as of September 30, 2020, compared to $143.1 million as of December 31, 2019. The increase was primarily the result of Neoleukin’s July financing in which the company raised $71.3 million in net proceeds.

Based upon its current operating plan, Neoleukin believes that its cash-on-hand will be sufficient to fund operations into 2023.

R&D Expenses: Research and development expenses for the third quarter of 2020 increased to $6.2 million from $1.4 million for the third quarter of 2019. This increase resulted primarily from ongoing development of NL-201 and excludes $47.7 million of acquired in-process R&D in the third quarter of 2019.

G&A Expenses: General and administrative expenses for the third quarter of 2020 decreased to $3.9 million from $10.4 million for the third quarter of 2019. Higher G&A expenses in the third quarter of 2019 were primarily due to one-time severance costs and the recognition of stock-based compensation expense for certain options that vested as a result of the merger between Neoleukin Therapeutics, Inc. (“Former Neoleukin”) and Aquinox Pharmaceuticals, Inc. (“Aquinox”).

Acquired in-process R&D: The acquired in-process research and development expense arose from the merger between Former Neoleukin and Aquinox in 2019 and was expensed immediately as management determined that the asset has no alternative future use in accordance with ASC 730.

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 third quarter of 2020 was $2.2 million compared to a net loss of $59.1 million in the third quarter of 2019. The net loss in the third quarter of 2019 included the significant acquired in-process R&D recognized in the period. Furthermore, net loss was reduced in the third quarter of 2020 due to the recognition of the gain on sale of Aquinox Canada.

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 has demonstrated the ability of NL-201 to stimulate and expand CD8+ and NK cells at very 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, receipt or timing of regulatory approval, use and adequacy of cash reserves, the therapeutic properties and potential of the company's de novo protein design technology, the potential benefits of the company's product candidates and platform. 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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NEOLEUKIN THERAPEUTICS INC.

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

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Assets		
Cash and cash equivalents	$ 201,150	$ 143,093
Other current assets	5,439	503
Other non-current assets	15,101	3,427
Total assets	$ 221,690	$ 147,023
Liabilities		
Current liabilities	$ 9,892	$ 4,743
Non-current liabilities	11,458	593
Total liabilities	21,350	5,336
Stockholders' equity	200,340	141,687
Total liabilities and stockholders' equity	$ 221,690	$ 147,023

NEOLEUKIN THERAPEUTICS, INC.

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

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	**2019**	**2020**	**2019**
Operating loss				
Research and development	$ 6,216	$ 1,420	$ 16,557	$ (471)
Acquired in-process research and development	-	47,716	-	47,716
General and administrative	3,860	10,380	12,359	15,358
Gain on sale of Aquinox Canada	(7,826)	-	(7,826)	-
Total operating loss	2,250	59,516	21,090	62,603
Other income, net	1	384	453	1,262
Net loss	$ (2,249)	$ (59,132)	$ (20,637)	$ (61,341)
Net loss per common stock – basic and diluted	$ (0.04)	$ (2.26)	$ (0.41)	$ (2.51)
Basic and diluted weighted average common shares outstanding	54,121,676	26,185,839	50,896,014	24,429,893

Source: Neoleukin Therapeutics, Inc.