May 4, 2017

NewLink Genetics Reports First Quarter 2017 Financial Results and Updates Clinical Trial Guidance

Management to Host Conference Call Today at 8:30 a.m. ET

AMES, Iowa, May 04, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), today reported consolidated financial results for the first quarter 2017, as well as progress in its clinical development programs.

Recent Highlights:

- Presented promising interim Phase 2 data of the IDO pathway inhibitor, indoximod, in combination with KEYTRUDA® (pembrolizumab) for patients with advanced melanoma at the American Association of Cancer Research (AACR) plenary session on April 4, 2017
- Presented a poster on NLG802, "*A novel prodrug of indoximod with enhanced pharmacokinetic properties,"* at AACR on April 4, 2017
- Abstract accepted for presentation at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) for a randomized double-blind, placebo-controlled Phase 2 study of indoximod in combination with the vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer
- Abstract accepted for presentation at the 2017 ASCO Annual Meeting submitted by our partner on a Phase 1b dose-escalation study of navoximod (GDC-0919) in combination with TECENTRIQ ® (atezolizumab) in multiple solid tumors

"We believe that the emerging clinical data from NewLink Genetics and other companies are validating the fundamental hypothesis that the IDO pathway is central to immuno-suppression in cancer," said Charles J. Link, Jr. MD, Chairman, Chief Executive Officer and Chief Scientific Officer. "We have two distinct IDO pathway inhibitors advancing in the clinic, indoximod - which is wholly-owned by NewLink Genetics - and navoximod (GDC-0919), which is partnered to Genentech/Roche. In addition, we have a next-generation compound, a novel prodrug of indoximod, NLG802, which we expect to enter the clinic by the end of Q3 this year."

Guidance for remainder of 2017:

- Metastatic castration resistant prostate cancer: Randomized, placebo-controlled Phase 2 clinical trial data to be presented at ASCO on Monday, June 5, 2017
- Metastatic pancreatic cancer: Indoximod in combination with gemcitabine + ABRAXANE® (nab-paclitaxel) Phase 2 trial to be presented at an upcoming medical meeting in the second half of 2017
- Acute Myeloid Leukemia (AML): Interim data from a Phase 1b dose-escalation study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed AML to be presented second half of 2017

The Company announced that it intends to initiate a pivotal trial of indoximod plus anti-PD-1 inhibitors for patients with advanced melanoma by the end of 2017. The trial is expected to use an adaptive design that incorporates a brief dose confirmation stage followed by a definitive randomized stage.

"The clinical data for indoximod in advanced melanoma establishes the basis for this pivotal trial," said Nicholas N. Vahanian, MD, President and Chief Medical Officer.

Financial Results:

Cash Position: NewLink Genetics ended the first quarter with cash and cash equivalents totaling $118.2 million compared to $131.5 million for the year ending December 31, 2016.

We expect to end 2017 with approximately $75 million in cash and equivalents, which excludes any cash that may be received from financings or milestones.

R&D Expenses: Research and development expenses were $15.7 million in the first quarter of 2017 compared to $21.9

million in the first quarter of 2016. The decrease was due primarily to a $4.6 million decline in clinical trial and manufacturing-related spend, a decrease in personnel-related spend of $1.4 million, and a decrease in licensing and consulting fees of $1.0 million, offset by an increase in stock compensation expense of $822,000.

G&A Expenses: General and administrative expenses in the first quarter of 2017 were $8.2 million compared to $9.2 million in the first quarter of 2016. The decrease was due to a decline of $700,000 in consulting and legal fees, a decrease of $700,000 in personnel-related spend, offset by an increase in stock compensation expense of $437,000.

Net Loss: NewLink Genetics reported a net loss of $20.9 million or loss of $0.72 per diluted share for the first quarter of 2017 compared to a net loss of $23.7 million or loss of $0.82 per diluted share for the first quarter of 2016.

NewLink Genetics ended Q1 2017 with 29,219,661 shares outstanding.

Conference Call and Webcast Details:

The Company has scheduled a conference call and webcast for 8:30 a.m. ET today to discuss the results and to give an update on clinical and business development activities. NewLink Genetics' senior management team will host the call, which will be open to all listeners. There will also be a question and answer session following the prepared remarks.

Access to the live conference call is available by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) five minutes prior to the start of the call. The conference call will be webcast live and a link to the webcast can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "Events and Presentations." To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast. A replay of the call will be available approximately two hours after the completion of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 7503837. The replay will be available for two weeks from the date of the call.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat cancer. For more information, please visit http://www.newlinkgenetics.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about NewLink Genetics' financial guidance for 2017; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2016 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this press release.

Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2017	2016
Grant revenue	$ 2,586	$ 4,338
Licensing and collaboration revenue	175	1,370
Total operating revenues	2,761	5,708
Operating expenses:		
Research and development	15,725	21,937
General and administrative	8,234	9,164
Loss from operations	(21,198)	(25,393)
Other (expense) income, net	(25)	39
Net loss before taxes	(21,223)	(25,354)
Income tax benefit	310	1,634
Net loss	$ (20,913)	$ (23,720)
Basic and diluted loss per share	$ (0.72)	$ (0.82)
Basic and diluted average shares outstanding	29,213,488	28,856,944

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	Year Ended	
	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 118,240	$ 131,490
Prepaid expenses and other current assets	8,984	5,921
Income tax receivable	6,287	5,975
Other receivables	9,645	24,526
Total current assets	143,156	167,912
Property and equipment, net	6,466	6,835
Total assets	$ 149,622	$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 27,423	$ 37,192
Unearned revenue	223	391
Other current liabilities	325	322
Total current liabilities	27,971	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	229	285
Deferred rent	1,068	1,091
Total long-term liabilities	7,297	7,376
Total liabilities	35,268	45,281
Stockholders' equity:		
Common stock	292	292
Additional paid-in capital	301,573	295,535
Treasury stock, at cost	(1,090)	(853)
Accumulated deficit	(186,421)	(165,508)
Total stockholders' equity	114,354	129,466
Total liabilities and stockholders' equity	$ 149,622	$ 174,747

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