July 28, 2017

NewLink Genetics Reports Second Quarter 2017 Financial Results and Updates Indoximod Program

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

AMES, Iowa, July 28, 2017 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today reported consolidated financial results for the second quarter of 2017 and provided updates on its clinical development program for indoximod, NewLink Genetics' small molecule targeting the IDO pathway with a distinct mechanism of action.

"We continue to focus on indoximod, our leading drug candidate, as it advances into late-stage clinical development," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "We have made great progress since the end of the first quarter. We have strengthened the IP around this program with the USPTO Notice of Allowances for indoximod salts and prodrug formulations, and NLG802 entered the clinic."

Recent Highlights:

- NewLink Genetics recently completed a successful face-to-face meeting with the FDA to review the proposed design for the pivotal trial with indoximod for patients with advanced melanoma.
- First patient dosed in the Phase 1 study of NLG802, a novel prodrug of indoximod. NLG802 is a distinct investigational agent targeting the IDO pathway and represents an important step in the Company's product life-cycle planning.
- A Notice of Allowance (NOA) by the US Patent and Trade Office (USPTO) was received in early July for our patent application covering indoximod salts and prodrugs. When issued, this patent will provide exclusivity until 2036 and cover both the formulation of indoximod to be used in the pivotal trial and NLG802.
- Phase 2 data from a randomized trial of indoximod in combination with the cancer vaccine, PROVENGE® (sipuleucel-T), for patients with metastatic castration resistant prostate cancer (mCRPC) were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on June 5th. These data showed a statistically significant improvement in radiographic progression-free survival (rPFS) of 10.3 months compared to 4.1 months in the placebo arm, with no difference in adverse events between the two arms.
- Phase 1b data from a trial of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML) were presented at the European Hematology Association (EHA) Annual Congress on June 23rd. These early data showed that after one cycle of induction therapy, 7/7 patients who achieved complete response (CR) were seen to have no evidence of minimal residual disease (MRD-neg), suggesting that the addition of indoximod has the potential to reduce the proportion of patients with evidence of leukemia after initial therapy.

Guidance for remainder of 2017:

- First patients dosed with novel salt formulation of indoximod.
- Updated data from Phase 2 trial of indoximod plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer to be presented at an oncology meeting in late 2017 or early 2018.
- Initiation of a pivotal trial of indoximod in combination with PD-1 checkpoint blockade for patients with advanced melanoma, with the goal of full enrollment by end of 2018.

Financial Results for the Three-Month Period Ended June 30, 2017

Cash Position: NewLink Genetics ended the second quarter with cash and cash equivalents totaling $107.8 million compared to $131.5 million for the year ending December 31, 2016.

R&D Expenses: Research and development expenses were $18.2 million in the second quarter of 2017 compared to $27.4 million in the second quarter of 2016. The decrease was due primarily to a $1.8 million decline in clinical trial spend, a decrease in supplies and other expense of $6.8 million, a decrease in personnel-related spend of $2.2 million, offset by an increase in manufacturing-related spend of $1.3 million, and an increase in licensing and consulting fees of $300,000.

G&A Expenses: General and administrative expenses in the second quarter of 2017 were $8.9 million compared to $9.1 million in the second quarter of 2016. The decrease was due to a decline of $1.0 million in personnel-related spend, offset by an increase of $261,000 in consulting and legal fees, an increase in stock compensation expense of $64,000, and an increase in supplies and other expense of $387,000.

Net Loss: NewLink Genetics reported a net loss of $16.7 million or ($0.57) per diluted share for the second quarter of 2017 compared to a net loss of $32.4 million or ($1.12) per diluted share for the second quarter of 2016.

NewLink Genetics ended the quarter with 29,281,301 shares outstanding.

Financial Guidance and Upcoming Investor Meetings

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

We look forward to presenting at the Baird Healthcare Conference and the Cantor Fitzgerald Healthcare Conference in September in New York City.

Conference Call Details

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update. 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 can be accessed through the NewLink Genetics website at http://investors.linkp.com/events.cfm. A replay of the call will be available for two weeks from the date of the call and can be accessed by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and using the passcode 51432155.

About NewLink Genetics Corporation

NewLink Genetics is a late-stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. Indoximod is being evaluated in combination with treatment regimens including PD-1 checkpoint blockade, cancer vaccines, and chemotherapy across multiple indications such as melanoma, prostate cancer, acute myeloid leukemia, and pancreatic cancer. For more information, please visit http://www.newlinkgenetics.com

PROVENGE® is a registered trademark of Dendreon Pharmaceuticals LLC

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.

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

	Three Months Ended June 30,		Six Months Ended June, 30	
	2017	**2016**	**2017**	**2016**
Grant revenue	$ 10,314	$ 1,262	$ 12,900	$ 5,600
Licensing and collaboration revenue	56	750	231	2,120
Total operating revenues	10,370	2,012	13,131	7,720
Operating expenses:				
Research and development	18,200	27,410	33,925	49,347
General and administrative	8,897	9,130	17,131	18,294
Loss from operations	(16,727)	(34,528)	(37,925)	(59,921)
Other income (expense), net	1	60	(24)	99
Net loss before taxes	(16,726)	(34,468)	(37,949)	(59,822)
Income tax benefit	—	2,079	310	3,713
Net loss	$ (16,726)	$ (32,389)	$ (37,639)	$ (56,109)
Basic and diluted loss per share	$ (0.57)	$ (1.12)	$ (1.29)	$ (1.94)
Basic and diluted average shares outstanding	29,255,386	28,891,827	29,219,469	28,874,385

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

	Year Ended	
	June 30, 2017	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 107,777	$ 131,490
Prepaid expenses and other current assets	4,916	5,921
Income tax receivable	6,287	5,975
Other receivables	11,258	24,526
Total current assets	130,238	167,912
Property and equipment, net	5,886	6,835
Total assets	$ 136,124	$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,822	$ 37,192
Unearned revenue	167	391
Other current liabilities	314	322
Total current liabilities	26,303	37,905
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	173	285
Deferred rent	1,045	1,091
Total long-term liabilities	7,218	7,376
Total liabilities	33,521	45,281
Stockholders' equity:		

Common stock	292	292
Additional paid-in capital	306,556	295,535
Treasury stock, at cost	(1,098)	(853)
Accumulated deficit	(203,147)	(165,508)
Total stockholders' equity	102,603	129,466
Total liabilities and stockholders' equity	$ 136,124	$ 174,747

Investor Contact:

Lisa Miller

Director of Investor Relations

NewLink Genetics

(515) 598-2555

lmiller@linkp.com

Media Contact:

Andrew Mastrangelo

AVP, Public & Media Relations

LaVoieHealthScience

617-374-8800, ext. 108

amastrangelo@lavoiehealthscience.com

Primary Logo

Source: NewLink Genetics Corporation