



November 2, 2017

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

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

AMES, Iowa, Nov. 02, 2017 (GLOBE NEWSWIRE) -- [NewLink Genetics Corporation](#) (NASDAQ:NLNK) today reported consolidated financial results for the third quarter of 2017 and provided updates on its clinical development program for indoximod, NewLink Genetics' IDO pathway inhibitor with a distinct mechanism of action.

"We are pleased with the progress we have made advancing indoximod into our pivotal trial in melanoma. Additionally, the clinical collaboration with AstraZeneca in pancreatic cancer represents a significant step toward expanding the opportunity for indoximod beyond melanoma," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer, and Chief Scientific Officer. "In addition, we have recently raised new capital in an underwritten offering which significantly increases our ability to continue to execute and expand our clinical development programs."

Recent Highlights:

- | Established the design of our pivotal trial for patients with advanced melanoma. The Phase 3 trial will evaluate indoximod in combination with both approved PD-1 checkpoint inhibitors, KEYTRUDA[®] (pembrolizumab) and OPDIVO[®] (nivolumab), in approximately 600 patients with advanced melanoma. Co-primary endpoints of the study are Progression Free Survival (PFS) by RECIST criteria and Overall Survival (OS).
- | Phase 2 data for indoximod plus PD-1 checkpoint inhibitor KEYTRUDA (pembrolizumab) updated for the original 51-patient advanced melanoma cohort first presented at AACR in April demonstrated improvement in complete response rates. The Complete Response (CR) improved to 20% from 12% as the data matured, and the 12-month PFS by RECIST criteria was 56% with a median PFS (mPFS) of 12.9 months.
- | Entered a clinical collaboration agreement with AstraZeneca to evaluate the combination of indoximod and IMFINZI[™] (durvalumab), AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy in a randomized, placebo-controlled Phase 2 trial for patients with metastatic pancreatic cancer.
- | Indoximod was granted Orphan Drug Designation by the FDA for patients with Stage IIb-IV melanoma.
- | Dosed the first patients with the novel salt formulation of indoximod. As planned, this was done in the ongoing Phase 1b study of indoximod in combination with standard of care chemotherapy for patients with newly diagnosed Acute Myeloid Leukemia (AML). All subsequent trials will utilize the new formulation of indoximod.
- | Raised \$55.2 million net of expenses in underwritten public offering led by Bank of America Merrill Lynch and Stifel subsequent to the third quarter. During the third quarter, we raised an additional \$19.3 million net of expenses in an "at-the-market" facility, with Cantor Fitzgerald as agent.

Guidance for remainder of 2017 and 2018:

- | Initiate the Pivotal trial of indoximod in combination with PD-1 checkpoint blockade for patients with advanced melanoma, with the goal of enrollment by end of 2018.
- | Present final results of Phase 2 trial of indoximod plus checkpoint inhibitors for patients with advanced melanoma during 2018.
- | Present final results of Phase 2 trial of indoximod plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer at an oncology meeting 1H 2018.
- | Initiate the randomized Phase 2 trial of indoximod plus durvalumab plus gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer 1H 2018.

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

Cash Position: NewLink Genetics ended the third quarter with cash and cash equivalents totaling \$120.7 million compared to \$131.5 million for the year ending December 31, 2016.

R&D Expenses: Research and development expenses were \$18.5 million in the third quarter of 2017 compared to \$24.5 million in the third quarter of 2016. The decrease of \$6.0 million was due primarily to a \$6.2 million decline in contract research and manufacturing spend, a \$500,000 decrease in personnel-related spend, and a \$530,000 decline in clinical trial and other supplies, offset by an increase of \$630,000 in one-time restructuring expense incurred for employee severance during the third quarter of 2017, an increase in legal and consulting spend of \$370,000, and an increase in stock compensation expense of \$230,000.

G&A Expenses: General and administrative expenses in the third quarter of 2017 were \$7.9 million compared to \$7.7 million in the third quarter of 2016. The increase of \$200,000 was due to a one-time restructuring expense incurred for employee severance during the third quarter of 2017 of \$1.1 million, an increase of \$370,000 for supplies and other expenses, and an increase in stock compensation expense of \$260,000 offset by a decline of \$1.1 million in personnel-related spend, and a decline of \$430,000 in consulting and legal fees.

Net Loss: NewLink Genetics reported a net loss of \$20.6 million or \$0.69 per diluted share for the third quarter of 2017 compared to a net loss of \$15.5 million or \$0.54 per diluted share for the third quarter of 2016.

NewLink Genetics ended the quarter with 31,319,751 shares outstanding.

Financial Guidance and Upcoming Investor Meetings

We expect to end 2017 with approximately \$150 million in cash and equivalents.

We look forward to presenting at the Stifel Healthcare Conference in New York City on November 14th and the Jefferies Healthcare Conference in London on November 16th.

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 <https://edge.media-server.com/m6/p/3exk7kmc>. 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 6198669.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape.

NewLink Genetics is currently evaluating indoximod in multiple combination studies for patients with various types of cancer including melanoma, pancreatic cancer and other malignancies.

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 anti-PD-1/PD-L1 agents, cancer vaccines, and chemotherapy across multiple indications such as melanoma, pancreatic cancer and other malignancies. For more information, please visit www.newlinkgenetics.com and follow us on Twitter [@NLNKGenetics](https://twitter.com/NLNKGenetics).

KEYTRUDA[®] is a registered trademark of Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

OPDIVO® is a registered trademark of Bristol-Myers Squibb Company.

IMFINZI™ is a registered trademark of AstraZeneca.

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.

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

	Three Months Ended September 30,		Nine Months Ended September, 30	
	2017	2016	2017	2016
Grant revenue	\$ 5,379	\$ 14,457	\$ 18,279	\$ 20,057
Licensing and collaboration revenue	103	888	334	3,008
Total operating revenues	5,482	15,345	18,613	23,065
Operating expenses:				
Research and development	18,480	24,463	52,405	73,810
General and administrative	7,907	7,749	25,038	26,043
Loss from operations	(20,905)	(16,867)	(58,830)	(76,788)
Other income (expense), net	160	19	136	118
Net loss before taxes	(20,745)	(16,848)	(58,694)	(76,670)
Income tax benefit	119	1,308	429	5,021
Net loss	<u>\$ (20,626)</u>	<u>\$ (15,540)</u>	<u>\$ (58,265)</u>	<u>\$ (71,649)</u>

Basic and diluted loss per share	\$ (0.69)	\$ (0.54)	\$ (1.98)	\$ (2.48)
Basic and diluted average shares outstanding	29,939,823	28,983,561	29,462,226	28,911,042

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

	Year Ended	
	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 120,702	\$ 131,490
Prepaid expenses and other current assets	2,701	5,921
Income tax receivable	114	5,975
Other receivables	10,670	24,526
Total current assets	<u>134,187</u>	<u>167,912</u>
Property and equipment, net	5,527	6,835
Total assets	<u>\$ 139,714</u>	<u>\$ 174,747</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 25,692	\$ 37,192
Unearned revenue	112	391
Other current liabilities	287	322
Total current liabilities	<u>26,091</u>	<u>37,905</u>
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	138	285
Deferred rent	1,021	1,091
Total long-term liabilities	<u>7,159</u>	<u>7,376</u>
Total liabilities	<u>33,250</u>	<u>45,281</u>
Stockholders' equity:		
Common stock	314	292
Additional paid-in capital	331,036	295,535
Treasury stock, at cost	(1,113)	(853)
Accumulated deficit	(223,773)	(165,508)
Total stockholders' equity	<u>106,464</u>	<u>129,466</u>
Total liabilities and stockholders' equity	<u>\$ 139,714</u>	<u>\$ 174,747</u>

Source: NewLink Genetics Corporation

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