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NewLink Genetics Provides Operational Update and Reports Fourth Quarter, Year End 2015 Financial Results

NewLink Genetics Outlines 2016 Business Priorities to Support Development of Immuno-Oncology Product Pipeline

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

AMES, Iowa, Feb. 29, 2016 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor programs, to improve the lives of patients with cancer, today reported business highlights and consolidated financial results for the fourth quarter and year ended 2015. NewLink Genetics also outlined key 2016 business priorities related to the clinical development programs for the company's immuno-oncology pipeline.

"During 2015, we made advances across multiple immuno-oncology clinical programs," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer and Chief Scientific Officer. "In 2016, we look forward to reporting top-line results of algenpantucel-L in the IMPRESS trial for patients with resected pancreatic cancer as well as fundamental validation of our IDO pathway inhibitor programs."

2015 Highlights

- | Reported continued progress of the pivotal, Phase 3 **IM**munotherapy for **Pancreatic RE**sectable cancer **St**udy (IMPRESS) trial of algenpantucel-L, for patients with resected pancreatic cancer.
- | Attracted top biotechnology talent to support increasing manufacturing capacities, the pre-commercialization efforts related to algenpantucel-L, and the expansion of clinical trial programs.
- | Completed enrollment in the **Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced Non-Resectable Cancer (PILLAR)** trial of algenpantucel-L for patients with locally advanced pancreatic cancer.
- | Presented Phase 1b/2 clinical data of indoximod in combination with temozolomide for patients with refractory malignant brain tumors at the Society of Neuro-Oncology Meeting, demonstrating evidence of clinical activity.
- | Completed enrollment in a randomized, Phase 2 trial with indoximod for patients with metastatic breast cancer and presented preliminary safety data at the San Antonio Breast Cancer Symposium.
- | Presented with Genentech, a member of the Roche Group, results from a Phase 1 study of GDC-0919 at ESMO/ECC. In addition, a Phase 1b, open-label, dose-escalation study of the safety and pharmacology of GDC-0919 in combination with atezolizumab for patients with advanced solid tumors began enrollment.
- | Added additional commercial oncology and clinical expertise to the board with the appointment of Mr. Paolo Pucci and Dr. Nicholas Vahanian.
- | Analysis of interim data from a Phase 3 ring vaccination trial in Guinea was published in the July 31st issue of *The Lancet*. NewLink Genetics was awarded an additional \$30.5 million in government funding to support the scale-up of manufacturing for the Ebola vaccine candidate, rVSV-ZEBOV, and other vaccine development initiatives.
- | Finished 2015 with \$197.8 million in cash and equivalents.

"In 2016, we anticipate significant progress toward milestones in our HyperAcute® Cellular Immunotherapy and IDO pathway inhibitor programs," said Nicholas Vahanian, M.D., President and Chief Medical Officer. "We are building an experienced oncology commercial team in anticipation of filing, registration, and product launch of algenpantucel-L. If approved, algenpantucel-L would be the first FDA-approved drug for patients with resected pancreatic cancer."

Anticipated Highlights in 2016

- | Top-line results of the pivotal, Phase 3 registration IMPRESS study for patients with resected pancreatic cancer expected this year.
- | Update on the timing of results in the PILLAR study for patients with locally advanced pancreatic cancer.
- | Report on additional clinical progress from the proprietary indoximod program in multiple indications in the following Phase 2 trials:
 - | Indoximod and gemcitabine/nab-paclitaxel for patients with metastatic pancreatic cancer.

- | Indoximod and ipilimumab or PD-1 inhibitors for patients with metastatic melanoma.
- | Indoximod and temozolomide for patients with refractory malignant brain tumors.
- | Indoximod and docetaxel or paclitaxel for patients with metastatic breast cancer.
- | Accelerate enrollment in a triple combination trial of tergenpumatumucel-L, indoximod and docetaxel for patients with advanced non-small cell lung cancer.
- | Update on the clinical progress of GDC-0919 combinations for patients with solid tumors by Genentech.
- | Update on progress and funding for the Zika vaccine program.

"The investments we made in 2015 advanced our pipeline of drug candidates, expanded our manufacturing capacity, and developed our pre-commercial sales and marketing infrastructure," said Jack Henneman, Executive Vice President and Chief Financial Officer. "NewLink Genetics enters 2016 in strong financial condition, positioned to support its strategic objectives of launching its lead product candidate and becoming a commercial biopharmaceutical company," added Mr. Henneman.

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2015, with cash, cash equivalents, and certificates of deposit totaling \$197.8 million compared to \$202.8 million for the year ending December 31, 2014. The decrease was attributable primarily due to the increased expenses for R&D and pre-commercialization development, offset by amounts received under government contracts and the \$20.0 million milestone payment from Merck in February 2015. The Company's cash position is sufficient to fund current operations in the near and medium term.

R&D Expenses: Research and development expenses were \$14.8 million and \$71.4 million in the fourth quarter and year ended December 31, 2015 compared to \$11.9 million and \$35.7 million during the comparable periods in 2014. The increase is primarily due to clinical trial expenses related to NewLink Genetics' broad pipeline of product candidates, as well as expenses for manufacturing and research related to the Ebola vaccine candidate. The majority of the Ebola-related expenses are subject to reimbursement under government contracts.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2015 were \$7.7 million and \$30.7 million compared to \$8.3 million and \$19.3 million during the comparable periods in 2014. The decrease from the quarter ended December 31, 2014 was primarily attributable to higher legal and consulting fees incurred in the fourth quarter of 2014 as compared to the fourth quarter of 2015. The increase from the year ended December 31, 2014 was primarily due to higher personnel-related costs as we prepare for potential commercialization, along with increases in share-based compensation expense, consulting and legal fees, travel expenses, and medical affairs and marketing.

Net Income/Loss: NewLink Genetics reported a net loss of \$21.6 million or a \$0.75 loss per diluted share for the fourth quarter of 2015 and a net loss of \$40.4 million or a \$1.41 loss per diluted share for the year ended December 31, 2015, compared to net income of \$120.0 million or \$3.83 earnings per diluted share for the fourth quarter of 2014 and net income of \$96.0 million or \$3.09 earnings per diluted share for the year ended December 31, 2014.

NewLink Genetics ended 2015 with 28,814,142 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 46732006. The replay will be available for two weeks from the date of the call.

HyperAcute® Cellular Immunotherapies

A unique, tumor-specific product candidates that take advantage of a pre-existing human immune response to initiate a powerful cascade, potentially educating the body's natural defenses to identify and destroy cancer cells. Unlike other immuno-oncology products, HyperAcute® Cellular Immunotherapies do not require patient tissue or cancer cells and are designed to be easy to administer. HyperAcute® Cellular Immunotherapies use allogeneic (disease-specific, not patient-

specific), tumor-specific human cell lines that have been modified to express alpha-gal. Intact, whole cells are used rather than cell fragments or purified proteins, which we believe results in the stimulation of a more powerful immune response. The company's most advanced clinical program utilizing this technology is for patients with pancreatic cancer. Additionally, there are on-going clinical development programs and data on induced immune responses targeting non-small-cell lung cancer, melanoma, prostate cancer and renal cancer.

Indoleamine 2,3-Dioxygenase (IDO) Checkpoint Inhibitors

The indoleamine 2,3-dioxygenase (IDO) pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. NewLink Genetics is researching two IDO pathway inhibitors, GDC-0919 (in partnership with Genentech) and indoximod, both small-molecule product candidates that have the potential to disrupt mechanisms by which tumors evade the immune system. NewLink Genetics' indoximod and GDC-0919 each have a distinct mechanism of action within the IDO pathway and are in Phase 1 and 2 clinical trials for a range of cancers, including breast cancer, melanoma, and other solid tumors.

Ebola Vaccine Program with Merck

NewLink Genetics is also working to address infectious diseases, such as Ebola and Zika. The Ebola vaccine candidate rVSV-ZEBOV (licensed to Merck & Co.) received the Best Prophylactic Vaccine award at the 15th Annual World Vaccine Congress on April 8, 2015, in Washington, DC. Interim results of a study in Guinea featured in the July issue of *The Lancet* showed potential efficacy with potential for both pre- and post-exposure use. NewLink Genetics and Merck received the Best Vaccine License award, which recognizes the business partnership with the greatest potential for success in bringing innovative medicines to market. rVSV-ZEBOV was originally developed by the Public Health Agency of Canada and was subsequently licensed to a wholly-owned subsidiary of NewLink Genetics.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. 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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements involve substantial risks and uncertainties. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," 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. The forward-looking statements in this press release include, among other things, statements regarding the following: NewLink Genetics' financial guidance for 2016; enrollment in or 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. The forward-looking statements in this press release represent NewLink Genetics' views as of the date of this press release. Although NewLink Genetics believe that the expectations reflected in the forward-looking statements contained herein are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause NewLink Genetics', or its industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the caption "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2014 and subsequent reports filed with the U.S. Securities and Exchange Commission. NewLink Genetics 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 has no current intention of doing so, even if new information becomes available, except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Grant revenue	\$ 6,064	\$ 3,295	\$ 32,358	\$ 6,642
Licensing and collaboration revenue	1,588	165,950	36,143	165,950
Total revenue	7,652	169,245	68,501	172,592
Operating expenses:				
Research and development	14,795	11,933	71,414	35,691
General and administrative	7,682	8,283	30,689	19,328
Income (loss) from operations	(14,825)	149,029	(33,602)	117,573
Other income (expense), net	(11)	15	(41)	60
Net (loss) income before taxes	(14,836)	149,044	(33,643)	117,633
Income tax expense	(6,738)	(29,029)	(6,738)	(21,616)
Net (loss) income	<u>\$ (21,574)</u>	<u>\$ 120,015</u>	<u>\$ (40,381)</u>	<u>\$ 96,017</u>
Basic (loss) earnings per share	<u>\$ (0.75)</u>	<u>\$ 4.29</u>	<u>\$ (1.41)</u>	<u>\$ 3.45</u>
Diluted (loss) earnings per share	<u>\$ (0.75)</u>	<u>\$ 3.83</u>	<u>\$ (1.41)</u>	<u>\$ 3.09</u>
Basic average shares outstanding	<u>28,788,615</u>	<u>27,965,055</u>	<u>28,586,585</u>	<u>27,838,873</u>
Diluted average shares outstanding	<u>28,788,615</u>	<u>31,345,654</u>	<u>28,586,585</u>	<u>31,025,099</u>

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

	Year Ended	
	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 197,800	\$ 202,797
Prepaid expenses and other current assets	10,342	12,062
Income tax receivable	—	8,763
Total current assets	208,142	223,622
Property and equipment, net	10,400	7,599
Total assets	<u>\$ 218,542</u>	<u>\$ 231,221</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,422	\$ 11,779
Unearned revenue	892	12,966
Other current liabilities	667	276
Income taxes payable	859	—
Total current liabilities	14,840	25,021
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	368	941
Deferred rent	1,153	1,238
Unearned revenue, excluding current portion	407	1,085
Total long-term liabilities	7,928	9,264
Total liabilities	22,768	34,285
Stockholders' equity:		
Common stock	288	280
Additional paid-in capital, net	276,610	236,838
Treasury stock, at cost	(771)	(222)
Retained deficit	(80,353)	(39,960)
Total equity	195,774	196,936
Total liabilities and equity	<u>\$ 218,542</u>	<u>\$ 231,221</u>

Corporate Contact:

Jack Henneman

Chief Financial Officer

(515) 598-2561

Investor@linkp.com

Investor Contact:

Donna LaVoie or Rachel Girard

LaVoieHealthScience

617-374-8800, ext. 107/102

dlavoie@lavoiehealthscience.com

rqirard@lavoiehealthscience.com

Media:

David Connolly

LaVoieHealthScience

617-374-8800, ext. 108

dconnolly@lavoiehealthscience.com

 Primary Logo

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