February 26, 2015

NewLink Genetics Corporation Provides Operational Update and Reports Fourth Quarter and Year End 2014 Financial Results

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

AMES, Iowa, Feb. 26, 2015 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (Nasdaq:NLNK), a biopharmaceutical company focused on bringing novel immunotherapeutic medicines to cancer patients globally, today announced operational, clinical and financial results for the fourth quarter and year ended December 31, 2014.

"2014 was a pivotal year for our company, and we advanced significantly across all areas of our business and most importantly toward our goal to bring new cancer therapies to patients," said Charles J. Link, Jr., M.D., Chairman, Chief Executive Officer and Chief Scientific Officer of NewLink Genetics. "Our pivotal, Phase 3 **IM**munotherapy for **P**ancreatic **RES**ectable cancer **S**tudy, called 'IMPRESS,' is nearing the second interim readout, and we will report when available. We are preparing to commercialize this innovative immunotherapy in the United States ourselves, and we are starting to lay the commercial groundwork that will allow us to accelerate access to algenpantucel-L, if approved by the FDA," said Dr. Link.

"Also, in 2014, we partnered our IDO inhibitor platform with Genentech and received an upfront payment of $150 million and have launched both preclinical drug discovery and clinical development teams that are already hard at work on this collaboration," said Nick Vahanian, M.D., President and Chief Medical Officer. "In the infectious disease area, we entered into a collaboration agreement with Merck with our Ebola vaccine candidate licensed from the Public Health Agency of Canada, which included a $30 million upfront payment. Within this collaboration, which includes multiple U.S. and international agencies, we have conducted multiple clinical trials, developed the capacity to manufacture it in quantity, and received substantial support from both the U.S. Department of Defense and the Department of Health and Human Services."

Program Updates:

HyperAcute® Cancer Immunotherapy Programs

NewLink Genetics' proprietary cancer immunotherapy programs may prove to have broad potential across a spectrum of cancer indications. NewLink Genetics has multiple HyperAcute immunotherapy programs in various stages of development, including pancreatic and lung cancer.

Algenpantucel-L for Patients with Pancreatic Cancer

The Phase 3 pivotal trial, known as IMPRESS, is designed to study standard adjuvant therapy alone or in combination with algenpantucel-L in patients who have undergone surgical resection for pancreatic cancer. This study is fully enrolled, and the first interim analysis previously has been reported.

- The Company revised its timing expectations and stated today that it expects to report on the second interim analysis in the first or second quarter of 2015. The possible outcomes for the second interim look include confirmation of continuing the study as designed to the pre-planned endpoint. The alternative outcome is a decision to proceed with filing with the FDA on the basis of the interim data due to improvement in overall survival rate as determined by the early stopping rules in the trial's Special Protocol Assessment.

The Phase 3 pivotal trial, known as **P**ancreatic **I**mmunotherapy with algenpantucel-**L** for **L**ocally **A**dvanced non-**R**esectable disease or PILLAR is currently enrolling patients.

- The Company reported that it expects to complete enrollment in the second half of 2015. When enrollment is completed, NewLink Genetics will provide guidance on the reporting of the preliminary results.

Tergenpumatucel-L for Patients with Advanced Lung Cancer

Tergenpumatucel-L, NewLink Genetics' HyperAcute Lung Immunotherapy, is being tested in a randomized, Phase 2b study in advanced lung cancer. An update on this program will be provided in the second half of 2015.

IDO/TDO Pathway Inhibitor Programs

In October 2014, the Company announced that it entered into an exclusive, worldwide license agreement with Genentech for the development and commercialization of NLG919, a clinical stage IDO (indoleamine 2,3-dioxygenase) pathway inhibitor, and collaboration for the discovery of the next generation IDO/TDO (tryptophan 2,3-dioxygenase) inhibitors to be developed and commercialized under the agreement. This alliance with Genentech brought NewLink Genetics $150 million in an upfront payment, plus potential milestone payments that exceed $1 billion, royalties and co-promotion rights as well as financial support for NewLink Genetics' work in the collaboration.

- Since announcing this alliance, NewLink Genetics and Genentech have launched both preclinical drug discovery and clinical development teams, which are already hard at work on the collaboration.
- In addition, the Company confirmed that it will continue the development of indoximod, including studies in combination with HyperAcute product candidates. The Company expects to complete enrollment of four different oncology trials by the first half of 2016.

Ebola Vaccine Program with Merck

In addition to the $30 million received in an upfront payment from Merck in November 2014, last week, the Company announced that it earned a $20 million milestone payment relating to the initiation of a pivotal clinical trial in Africa and it has the ability to earn royalties on future potential sales of the vaccine, if approved by regulatory agencies in specified countries based on certain economic criteria.

- The Company is currently collaborating with the Public Health Agency of Canada, the National Institutes of Health, the Center for Disease Control, the United States Department of Defense, and multiple international agencies and is conducting multiple clinical trials around the world.
- In 2014, the Company announced that it received significant funding from the Department of Defense and the Biomedical Advanced Research and Development Authority to support the manufacturing of the vaccine at various dose levels as well as early clinical trials and important groundwork needed to move the candidate to effectiveness trials.
- Dr. Thomas P. Monath, a top vaccine expert was hired to lead NewLink Genetics' infectious disease effort and is building its organization in the Boston area to support this important initiative.

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2014, with cash, cash equivalents, and certificates of deposit totaling $202.8 million compared to $61.5 million for the year ending December 31, 2013. The increase was attributable primarily to the upfront payments for the Genentech and Merck alliances, net of taxes, and amounts received under government contracts.

R&D Expenses: Research and development expenses in the fourth quarter of 2014 were $11.9 million and $35.7 million for the year ended December 31, 2014 compared to $5.2 million and $22.7 million during the comparable periods in 2013. The increase is primarily due to increases in clinical trial and manufacturing expenses.

G&A Expenses: General and administrative expenses in the fourth quarter of 2014 were $8.3 million and $19.3 million for the year ended December 31, 2014 compared to $3.0 million and $9.5 million during the comparable periods in 2013. The increase was primarily due to an increase in share-based compensation expense, as well as increases in consulting and legal fees, travel expenses, and medical affairs and marketing.

Net Income/Loss: NewLink Genetics reported net income of $126.9 million or $4.05 per diluted share for the fourth quarter of 2014 and $102.9 million or $3.32 per diluted share for the year ended December 31, 2014 compared to a net loss of $8.0 million or $0.31 per diluted share and $31.2 million or $1.23 per diluted share for the comparable periods in 2013.

NewLink Genetics received gross proceeds from sales under its at-the-market offering (ATM) of approximately $27.7 million in 2014 and ended 2014 with 27,980,849 shares outstanding.

Financial Guidance

NewLink Genetics expects to end the year on December 31, 2015 with approximately $160 million in cash, cash equivalents and certificates of deposit. The Company anticipates that this is enough cash to fund current operations near and medium term, but will file a new shelf registration statement to give the company the option to react quickly to market conditions. This also recognizes that an early halt in the IMPRESS trial for effectiveness would require the need to accelerate organizational development and spending levels.

"We finished the year with a strong cash position and the capacity to make the necessary investments to become a commercial biopharmaceutical company," said Jack Henneman, Executive Vice President and Chief Financial Officer. "Significant investments in 2015 will include increasing our manufacturing capacity, developing our commercial sales and marketing teams, and investments in broadening our pipeline of drug candidates."

Conference Call

The Company has scheduled a conference call for 8:30 a.m. ET today to discuss the results and to give an update on clinical and business development activities.

NewLink's senior management team will host the conference 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 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 call can also be accessed through a webcast via a link provided on the Investors and Media homepage of NewLink's website at www.NewLinkGenetics.com. 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 88421787. The replay will be available for two weeks from the date of the call, and the webcast will also be archived on the website.

About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. NewLink's 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 without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, 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 2015; enrollment in its clinical trials for product candidates based on NewLink's HyperAcute and IDO platform technologies; its timing of release of clinical 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, 2013, Form S-3 Registration Statement filed December 28, 2012 and in its other filings with the Securities and Exchange Commission. 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 Dec. 31,		Year Ended Dec. 31,	
	2014	2013	2014	2013
Grant revenue	$ 3,295	$ 294	$ 6,642	$ 1,093
Licensing revenue	165,950	—	165,950	—

Total revenue	169,245	294	172,592	1,093
Operating expenses:				
Research and development	11,931	5,208	35,691	22,713
General and administrative	8,284	2,999	19,328	9,521
Income (loss) from operations	149,030	(7,913)	117,573	(31,141)
Other income (expense), net	13	(3)	60	91
Income (loss) before income taxes	149,043	(7,916)	117,633	(31,050)
Income tax expense	(22,188)	(130)	(14,775)	(130)
Net income (loss)	$ 126,855	$(8,046)	$ 102,858	$(31,180)
Basic earnings per share	$ 4.54	$(0.31)	$ 3.69	$(1.23)
Diluted earnings per share	$ 4.05	$(0.31)	$ 3.32	$(1.23)
Basic average shares outstanding	27,956,055	25,890,638	27,838,873	25,275,179
Diluted average shares outstanding	31,345,654	25,890,638	31,025,099	25,275,179

NewLink Genetics Corporation

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	Year Ended	
	December 31, 2014	**December 31, 2013**
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 202,797	$ 61,540
Prepaid expenses, advance payments to vendors and other current assets	12,062	2,430
Income tax receivable	15,604	—
Total current assets	230,463	63,970
Property and equipment, net	7,599	6,587
Total assets	$ 238,062	$ 70,557
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 11,779	$ 3,473
Unearned revenue	12,966	—
Other current liabilities	357	403
Total current liabilities	25,102	3,876
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	860	1,033
Deferred rent	1,238	1,321
Unearned revenue, excluding current portion	1,085	—
Total long-term liabilities	9,183	8,354
Total liabilities	34,285	12,230
Stockholder's equity:		
Common stock	280	266
Additional paid-in capital, net	236,838	194,038
Treasury stock, at cost	(222)	—
Retained deficit	(33,119)	(135,977)

Total equity	203,777	58,327
Total liabilities and equity	$ 238,062	$ 70,557

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