May 6, 2014

NewLink Genetics Corporation Reports First Quarter 2014 Financial Results

AMES, IA -- (Marketwired) -- 05/06/14 -- NewLink Genetics Corporation (NASDAQ: NLNK) today reported consolidated financial results for the first quarter of 2014 and progress in its development programs.

"In 2013, we achieved a major milestone when we completed patient enrollment in our algenpantucel-L pivotal Phase 3 IMPRESS study," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. Following completion of the first interim analysis in March of this year, the NewLink Genetics' Independent Data Safety Monitoring Committee (DSMC) reviewed patient data and, as anticipated, recommended study continuation without modification. A second interim analysis is planned upon reaching 333 patient events and, if needed, a final analysis is planned at 444 patient events. "We continue to look forward to the second interim analysis of our IMPRESS study near the end of this year and, assuming positive data, we plan to file a BLA for algenpantucel-L in 2015," said Dr. Link.

During 2014, the Company plans to continue advancing product development efforts across both HyperAcute and IDO pathway inhibitor platforms. Currently NewLink has six HyperAcute vaccines in various stages of clinical development for multiple indications (pancreas, lung, melanoma, prostate, breast and renal). In 2014, the Company continued expanding the breadth and depth of its IDO pathway inhibitor program. This included additional clinical development for its lead product candidate, indoximod, and also initiation of patient enrollment in a first-in-human clinical study of NLG919, its second compound from this platform.

"During the first quarter of 2014 at AACR we presented promising pre-clinical data demonstrating the synergistic anti-tumor activity of our IDO pathway inhibitors indoximod and NLG919 in combination with other checkpoint inhibitors and cancer immunotherapies," commented Dr. Nicholas Vahanian, President and Chief Medical Officer of NewLink. "At the same meeting, we also presented pre-clinical data on a novel class of anti-cancer agents called TDO inhibitors, which are structurally and functionally related to IDO."

NewLink reported a net loss of $9.2 million or ($.33) per share for the first quarter of 2014 compared to a net loss of $7.9 million or ($.33) per share for the comparable period in 2013.

Research and development expense in the first quarter of 2014 was $6.4 million compared to $6.3 million during the comparable period in 2013. The increase was primarily due to an increase in personnel-related expenses, offset by a decrease in contract research, manufacturing and consulting fees.

General and administrative expense in the first quarter of 2014 was $3.3 million compared to $2.0 million during the comparable period in 2013. The increase was primarily due to an increase in share-based compensation expense.

NewLink ended the quarter on March 31, 2014 with cash, cash equivalents, and certificates of deposit totaling $84.0 million and expects to end the year with approximately $40 million in cash, cash equivalents and marketable securities. NewLink received gross proceeds from sales under its ATM of approximately $28.3 million in the first quarter of 2014. NewLink ended the first quarter of 2014 with 27,862,390 shares outstanding.

Recent Accomplishments

- *HyperAcute Platform.* Completed first interim analysis for Phase 3 IMPRESS clinical trial and DSMC recommended study continuation without modification. Continued advancing the platform across multiple indications including pancreas, lung, melanoma and renal cancer.
- *IDO Inhibitors.* Presented preclinical data at the American Association for Cancer Research (AACR) 2014 Annual Meeting demonstrating that combining multiple checkpoint inhibitors that target the IDO *(indoleamine-(2,3)-dioxygenase)* pathway is effective in reducing local tumor-mediated immunosuppression and providing potential for enhanced anti-tumor activity. These data demonstrated the synergistic effects of combining NLG919, indoximod and anti-PD-1/PD-L1/PD-L2 antibodies to block both the IDO and PD pathways resulting in enhanced anti-tumor effects compared to blocking each pathway independently. This synergy was demonstrated in the context of established tumors treated with otherwise ineffective chemo-immunotherapy regimens.

- *TDO Inhibitors.* A novel class of compounds that mediate TDO *(tryptophan-2,3-dioxygenase)* activity were also presented at the AACR meeting. These data showed novel compounds with potent and selective TDO inhibition as well as IDO-specific inhibition and dual inhibition of TDO and IDO.

About NewLink Genetics Corporation

NewLink 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's 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. For more information please visit http://www.linkp.com.

By leveraging its dual cancer immunotherapy platforms, which are designed to harness multiple components of the immune system to combat cancer, NewLink is well positioned to establish a leadership position in immuno-oncology. NewLink's HyperAcute® immunotherapy platform uniquely stimulates the patient's immune system to recognize and attack cancer cells, while its IDO pathway inhibitor platform technology targets a key immune checkpoint and disrupts mechanisms by which tumors evade the patient's immune system. NewLink's broad product pipeline includes biologic and small molecule immunotherapy product candidates designed to treat a wide range of oncology indications either as monotherapy or in combination with other treatment regimens. NewLink's most advanced product candidates include algenpantucel-L and tergenpumatucel-L HyperAcute immunotherapies, currently in Phase 3 clinical development for pancreatic cancer and Phase 2b/3 for non-small cell lung cancer, respectively. The IDO pathway inhibitor platform has two drug candidates currently in development. The first, indoximod, is currently in Phase 2 development for a range of solid tumor cancers. NewLink's second IDO pathway inhibitor, NLG919, is currently in Phase 1 development for advanced solid tumors. By targeting multiple immune system deficits, NewLink's product pipeline offers a broad approach to immuno-oncology.

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's financial guidance for 2014; 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's 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's 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's views as of any date subsequent to the date of this press release.

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

	Three Months Ended March 31,	
	2014	***2013***
Grant Revenue	$ 334	$ 302
Operating expenses:		
Research and development	6,387	6,343
General and administrative	3,251	2,001
Loss from operations	(9,304)	(8,042)

Other (expense) income, net	68	108
Net loss	$ (9,236)	$ (7,934)
Net loss per common share, basic and diluted	$ (0.33)	$ (0.33)
Weighted average common shares outstanding	27,605,910	23,860,469

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	March 31, 2014	***December 31, 2013***
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 83,962	$ 61,540
Prepaid expenses and other current assets	1,347	2,430
Total current assets	85,309	63,970
Property and equipment, net	6,434	6,587
Total assets	$ 91,743	$ 70,557
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,358	$ 3,603
Deferred rent	84	84
Other current liabilities	190	189
Total current liabilities	3,632	3,876
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	986	1,033
Deferred rent	1,300	1,321
Total long-term liabilities	8,286	8,354
Total liabilities	11,918	12,230
Stockholder's equity:		
Preferred stock	--	--
Common stock	279	266
Additional paid-in capital, net	224,941	194,038
Treasury Stock, at cost	(182)	--
Deficit accumulated during the development stage	(145,213)	(135,977)
Total equity	79,825	58,327
Commitments	--	--
Total liabilities and equity	$ 91,743	$ 70,557

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Source: NewLink Genetics Corporation