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NewLink Genetics Corporation Reports Third Quarter 2013 Financial Results

AMES, IA -- (Marketwired) -- 11/12/13 -- NewLink Genetics Corporation (NASDAQ: NLNK)

- *Completion of enrollment in pivotal Algenpantucel-L Pancreas Phase 3 trial, progressing enrollment in Phase 2 trial of indoximod and planned clinical trial initiation for our second IDO pathway checkpoint inhibitor drug, NLG919, demonstrate significant progress in both cancer immunotherapy technology platforms*

NewLink Genetics Corporation (NASDAQ: NLNK), today reported consolidated financial results for the third quarter of 2013 and reviewed progress in its development programs.

NewLink Genetics is a biopharmaceutical company that focuses on unleashing the potential of the human immune system through the discovery, development and commercialization of novel cancer immunotherapy products, to significantly improve treatment outcomes for patients with cancer. 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 cancer immunotherapy. 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 expected to enter clinical development in the fourth quarter of 2013. By targeting multiple immune system deficits, NewLink's product pipeline offers a broad approach to cancer immunotherapy.

NewLink reported a net loss for the third quarter 2013 of $8.1 million, increasing from $5.9 million for the third quarter 2012 due to a $1.3 million increase in research and development expense and a $900,000 increase in general and administrative expense. The weighted average common shares outstanding for the third quarter 2013 were 25.7 million, resulting in a loss per share of $.32, as compared to 20.9 million and $.28 per share for third quarter 2012. The increase in the number of weighted average common shares outstanding was primarily attributable to shares issued in NewLink's public offering in February 2013.

Research and development expense for the third quarter 2013 was $6.1 million compared with $4.8 million for the third quarter 2012. The increase was primarily due to increases in personnel and clinical trial expense. General and administrative expense for the third quarter 2013 was $2.3 million compared with $1.4 million for the third quarter 2012. The increase was primarily due to an increase in share-based compensation expense and legal and consulting fees.

NewLink ended the third quarter with cash and cash equivalents totaling $52.0 million and expects to end the year with more than $40 million in cash, cash equivalents and marketable securities.

"We achieved a major milestone in the IMPRESS Phase 3 clinical trial of algenpantucel-L with the successful accrual of 722 subjects with surgically resected pancreatic cancer. Completion of study enrollment is a critical step toward our mission of bringing better treatment options to pancreatic cancer patients who are in desperate need of more promising alternatives," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "We are evaluating the impact of tergenpumatucel-L in our ongoing Phase 2B/3 non-small-cell-lung cancer trial. In addition, we presented encouraging data demonstrating greater than expected responses to salvage chemotherapy subsequent to treatment with NewLink's proprietary HyperAcute immunotherapies in pancreatic and non-small-cell lung cancer. We plan to strengthen our position in IDO pathway inhibition by advancing our first compound, indoximod, further into its clinical development and by bringing our second product candidate, NLG919, to clinic later this year."

Third Quarter and Recent Accomplishments

- *Algenpantucel-L*. Completed patient enrollment of 722 patients with surgically resected pancreatic cancer in the

Phase 3 IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) clinical trial. Additionally, a second Phase 3 trial involving patients with locally advanced pancreatic cancer (PILLAR) is currently enrolling patients.

- *IDO (indoleamine-(2,3)-dioxygenase) Pathway Inhibition*. Enrollment of patients with metastatic breast cancer continues to advance in our randomized Phase 2 study of indoximod in combination with docetaxel. A Phase 1b dose-escalation study of indoximod plus docetaxel in patients with advanced solid tumors showed a favorable safety profile and preliminary signs of efficacy. NewLink plans to initiate a Phase 1 study of its second IDO pathway checkpoint inhibitor, NLG919, before the end of the year.

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. Patient information is available at http://www.pancreaticcancer-clinicaltrials.com.

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 2013; the timing for completion of enrollment of our Phase 3 clinical trial for our HyperAcute Pancreas cancer immunotherapy; the 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 or 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 period ended December 31, 2012, 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 Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Grant revenue	$ 265	$ 327	$ 799	$ 1,388
Operating expenses:				
Research and development	6,125	4,779	17,505	13,349
General and administrative	2,257	1,396	6,522	5,005
Loss from operations	(8,117)	(5,848)	(23,228)	(16,966)
Other (expense) income, net	(6)	(3)	94	(36)
Net loss	$ (8,123)	$ (5,851)	$ (23,134)	$ (17,002)
Net loss per common share, basic and diluted	$ (0.32)	$ (0.28)	$ (0.92)	$ (0.82)
Weighted average number of common				

shares outstanding	25,702,043	20,887,689	25,067,772	20,729,174

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

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 51,964	$ 21,744
Prepaid expenses and other current assets	2,185	1,645
Total current assets	54,149	23,389
Property and equipment, net	6,738	6,040
Total assets	$ 60,887	$ 29,429
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,842	$ 2,631
Other current liabilities	272	288
Total current liabilities	5,114	2,919
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable, obligations under capital leases	1,081	1,178
Deferred rent	1,342	1,405
Total long-term liabilities	8,423	8,583
Total liabilities	13,537	11,502
Stockholders' equity:		
Common stock	257	210
Additional paid-in capital, net	175,024	122,514
Deficit accumulated during the development stage	(127,931)	(104,797)
Total stockholders' equity	47,350	17,927
Total liabilities and equity	$ 60,887	$ 29,429

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Source: NewLink Genetics Corporation

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