August 7, 2013

NewLink Genetics Corporation Reports Second Quarter 2013 Financial Results

AMES, IA -- (Marketwired) -- 08/07/13 -- NewLink Genetics Corporation (NASDAQ: NLNK) today reported consolidated financial results for the second quarter of 2013 and reviewed progress in its development programs.

NewLink reported a net loss for the second quarter 2013 of $7.1 million or $.28 per common share (based on 25.6 million weighted average shares outstanding), compared with $6.3 million, or $.31 per common share, for the second quarter 2012 (based on 20.7 million weighted average shares outstanding).

Total grant revenues for the second quarter 2013 were $232,000 compared with $590,000 for the second quarter 2012. Research and development expense for the second quarter 2013 was $5.0 million compared with $4.7 million for the second quarter 2012. General and administrative expense for the second quarter 2013 was $2.3 million compared with $2.2 million for the second quarter 2012.

NewLink ended the second quarter with cash, cash equivalents and certificates of deposit totaling $59.0 million and continues to expect to end the year with about $40 million in cash, cash equivalents and marketable securities.

"We presented an array of compelling clinical and preclinical data across our pipeline of novel immunotherapies at some of the most prominent cancer meetings this quarter. This included clinical data on NewLink's HyperAcute immunotherapies and our novel IDO pathway inhibitor, indoximod. In addition, preclinical data on NLG919, our second IDO pathway inhibitor were presented at ACCR," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "Patient accrual remains on track for the many clinical trials currently underway, including enrollment in the Phase 3 IMPRESS trial for surgically resected pancreatic cancer. In addition, we have made significant progress in the Phase 2b/3 trial for patients with previously treated non-small-cell lung cancer and in Phase 2 trials in other settings. We look forward to reporting further progress with these programs in the months to come."

Second Quarter and Recent Accomplishments

Pipeline:

- *Algenpantucel-L*. Presented clinical data demonstrating encouraging long-term disease-free and overall survival in a Phase 2 clinical study of algenpantucel-L for resected pancreatic cancer at the American Society of Clinical Oncology (ASCO) 2013 Annual Meeting. Overall survival data from patients with elevated levels of two or more separate biomarkers correlated with a statistically significant improvement relative to those without elevated levels. NewLink's lead product candidate, algenpantucel-L, is being studied in a Phase 3 trial with enrollment of up to 722 patients with surgically resected pancreatic cancer (IMPRESS). Algenpantucel-L is also being tested in a second Phase 3 study involving patients with locally advanced pancreatic cancer (PILLAR).

- *Tergenpumatucel-L*. Presented positive clinical data demonstrating the potential to improve survival as well as enhancing response rates to subsequent therapies in a Phase 2 clinical study of tergenpumatucel-L for non-small cell lung cancer (NSCLC) at the ASCO 2013 Annual Meeting. In this study tergenpumatucel-L demonstrated activity as a single agent and the potential to enhance salvage chemotherapy efficacy in previously treated patients. Tergenpumatucel-L is the second most advanced product in clinical testing from NewLink's HyperAcute platform technology. In addition, a Phase 2b/3 trial comparing tergenpumatucel-L to docetaxel for patients with previously treated NSCLC is currently underway to further investigate tergenpumatucel-L's potential to produce a chemo-sensitization effect and improve overall survival.

- *Indoximod*. Presented clinical data demonstrating safety and anti-tumor activity in two Phase 1 studies of indoximod for metastatic tumors when used in combination with other anti-cancer agents. Indoximod was tested in a Phase 1 study in combination with docetaxel and in a Phase 1B/2 study in combination with a dendritic cell cancer vaccine (Ad.p53DC). In both studies, indoximod was well tolerated when combined with these anti-cancer agents and showed promising signs of anti-tumor activity. Indoximod is an orally administered small molecule drug candidate that inhibits the IDO pathway. Two randomized, placebo controlled Phase 2 clinical trials with indoximod in combination with other agents for patients with metastatic breast or prostate cancer are currently underway.

- *NLG919*. Presented preclinical data demonstrating the benefits of targeting the IDO pathway with small molecule

immunomodulatory drugs for the treatment of cancer at the 2013 Annual Meeting of the American Association for Cancer Research (AACR). These data demonstrated on target anti-tumor effects and synergy with indoximod as well as favorable oral bioavailability, pharmacokinetic and pharmacodynamic profiles. NLG919 is NewLink's second small molecule IDO pathway inhibitor and is expected to enter human clinical trials by the end of this year.

Corporate:

- Added to the NASDAQ Biotechnology Index ®, effective Monday, May 20, 2013. The NASDAQ Biotechnology Index tracks the performance of a select set of NASDAQ-listed biotechnology and pharmaceutical securities that meet certain eligibility criteria including a minimum market capitalization of $200 million and minimum average daily trading volume of 100,000 shares. The Index Securities serve as the basis for the iShares NASDAQ Biotechnology Index Fund.

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 June 30,		***Six Months Ended June 30,***	
	2013	***2012***	***2013***	***2012***
Grant revenue	$ 232	$ 590	$ 534	$ 1,061
Operating expenses:				
Research and development	5,037	4,740	11,380	8,570
General and administrative	2,264	2,151	4,265	3,609
Loss from operations	(7,069)	(6,301)	(15,111)	(11,118)
Other (expense) income, net	(8)	(8)	100	(33)
Net loss	$ (7,077)	$ (6,309)	$ (15,011)	$ (11,151)
Net loss per common share, basic and				

diluted	$ (0.28)	$ (0.31)	$ (0.61)	$ (0.54)
Weighted average number of common shares outstanding	25,620,566	20,684,944	24,745,380	20,649,045

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

	June 30, 2013	***December 31, 2012***
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	$ 59,039	$ 21,744
Prepaid expenses and other current assets	2,032	1,645
Total current assets	61,071	23,389
Property and equipment, net	5,942	6,040
Total assets	$ 67,013	$ 29,429
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,893	$ 2,631
Deferred rent	84	84
Other current liabilities	186	204
Total current liabilities	4,163	2,919
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	1,129	1,178
Deferred rent	1,363	1,405
Total long-term liabilities	8,492	8,583
Total liabilities	12,655	11,502
Stockholder's equity:		
Preferred stock	--	--
Common stock	257	210
Additional paid-in capital, net	173,909	122,514
Deficit accumulated during the development stage	(119,808)	(104,797)
Total stockholders' equity	54,358	17,927
Total equity	54,358	17,927
Commitments and contingencies	--	--
Total liabilities and equity	$ 67,013	$ 29,429

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Source: NewLink Genetics Corporation