



May 6, 2013

## **NewLink Genetics Corporation Reports First Quarter 2013 Financial Results**

AMES, IA -- (Marketwired) -- 05/06/13 -- NewLink Genetics Corporation (NASDAQ: NLNK), a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapies to improve treatment options for patients with cancer, today reported consolidated financial results for the first quarter of 2013.

"We are looking forward to completing patient accrual for our IMPRESS trial of algenpantucel-L for surgically resected pancreatic cancer. It was also encouraging to see additional clinical trials of both our HyperAcute and IDO product candidates advancing this past quarter," commented Dr. Charles Link, Chairman and Chief Executive Officer of NewLink. "In addition, NewLink presented preclinical results for our second IDO pathway inhibitor drug candidate, NLG919, at the American Association for Cancer Research annual meeting. Based on these data, we plan to initiate a clinical trial with NLG919 later this year, further expanding our clinical development programs."

### ***First Quarter and Recent Accomplishments***

Pipeline:

- | Demonstrated significant progress towards completing enrollment in our IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 trial with algenpantucel-L for patients with surgically resected pancreatic cancer. The primary endpoint for this open label, randomized, multi-centered, 722 patient trial is overall survival. As determined by Special Protocol Assessment (SPA), the first interim analysis will be conducted when 222 deaths are reported for the study.
- | Continued patient accrual in our randomized Phase 2B/3 trial comparing tergenpumatucel-L to docetaxel for patients with previously treated non-small cell lung cancer. We expect to add additional sites in the coming months for this trial which has a planned accrual of 240 patients.
- | Launched a randomized, placebo controlled Phase 2 study for patients with metastatic breast cancer evaluating the combination of docetaxel with NewLink's most advanced small molecule IDO pathway inhibitor, indoximod. This Phase 2 clinical study will enroll up to 120 patients and follows the successful Phase 1b dose-escalation study of indoximod in patients with advanced solid tumors in which a favorable safety profile and promising early signs of activity were observed.
- | Pre-clinical data on NLG919 demonstrating on target anti-tumor effects and synergy with indoximod were presented at the American Association for Cancer Research annual meeting. Favorable oral bioavailability, pharmacokinetic and pharmacodynamic profiles were also reported. NLG919 is NewLink's second small molecule IDO pathway inhibitor and, based on these data, is expected to enter human clinical trials by the end of this year.

Corporate:

- | Appointed Brian Wiley as Vice President Business Development and head of pre-commercialization activities for algenpantucel-L. Mr. Wiley has extensive oncology business development and commercialization experience within the pharmaceutical industry.
- | Closed Public Offering with aggregate net proceeds of approximately \$49.0 million providing NewLink with resources to advance its lead development programs to their next major data points.

### ***Upcoming Activities***

NewLink expects to present at the following conferences:

- | Jefferies 2013 Global Healthcare Conference taking place June 3-6 in NYC.
- | American Society of Clinical Oncology (ASCO) May 31 - June 4, 2013 in Chicago, IL.

### ***First Quarter 2013 Financial Results***

- | Cash, cash equivalents and certificates of deposit totaled \$64.0 million at March 31, 2013.
- | Total grant revenues for the first quarter 2013 were \$302,000 compared with \$471,000 for the first quarter 2012.
- | Research and development expense for the first quarter 2013 was \$6.3 million compared with \$3.8 million for the first

quarter 2012. The \$2.5 million increase was primarily due to increased manufacturing and clinical trial expense from the same period in 2012.

- 1 General and administrative expense for the first quarter 2013 was \$2.0 million compared with \$1.5 million for the first quarter 2012. This increase was primarily due to increases in personnel related expenses.
- 1 Net loss for the first quarter 2013 was \$7.9 million or \$.33 per common share (based on 23.9 million weighted average shares outstanding), compared with \$4.8 million, or \$.23 per common share, for the first quarter 2012 (based on 20.6 million weighted average shares outstanding). The difference in the number of weighted average shares outstanding primarily resulted from NewLink's public offering in February 2013.

### **Financial Guidance**

NewLink expects to end 2013 with about \$40 million in cash, cash equivalents and marketable securities.

### **About NewLink Genetics Corporation**

NewLink Genetics Corporation is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapies 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 monotherapies or in combination with other treatment regimens.

NewLink's lead product candidate, algenpantucel-L (HyperAcute<sup>®</sup> pancreas), is being studied in our IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 trial for patients with surgically resected pancreatic cancer (under a Special Protocol Assessment with the U.S. FDA). Algenpantucel-L is being tested in a second Phase 3 study (PILLAR, "Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable") for patients with locally advanced pancreatic cancer. NewLink is also testing tergenpumatumucel-L, an additional HyperAcute<sup>®</sup> product candidate, in an adaptive design randomized Phase 2B/3 clinical trial currently accruing up to 240 patients with non-small cell lung cancer.

NewLink is also actively developing two small-molecule, IDO (indoleamine-(2, 3)-dioxygenase) pathway inhibitors. The most advanced is indoximod, an orally bioavailable product candidate, that is being studied in various chemotherapy and immunotherapy combination clinical studies. NewLink's second IDO pathway inhibitor, NLG919, has shown promising preclinical results and is expected to enter clinical trials by the end of 2013. 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 Statement of Operations**  
**(unaudited)**  
**(In thousands, except share and per share amounts)**

**Three Months Ended**

	<b>March 31,</b>	
	<b>2013</b>	<b>2012</b>
Grant Revenue	\$ 302	\$ 471
Operating expenses:		
Research and development	6,343	3,830
General and administrative	2,001	1,458
Loss from operations	(8,042)	(4,817)
Other (expense) income, net	108	(25)
Net loss	<u>\$ (7,934)</u>	<u>\$ (4,842)</u>
Net loss attributable to NewLink	<u>\$ (7,934)</u>	<u>\$ (4,842)</u>
Net loss per common share, basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.23)</u>
Weighted average common shares outstanding	<u>23,860,469</u>	<u>20,613,146</u>

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

	<b>March 31,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012</b>
Assets		
Current assets:		
Cash, cash equivalents and certificates of deposit	\$ 64,025	\$ 21,744
Prepaid expenses and other current assets	1,741	1,645
Total current assets	<u>65,766</u>	<u>23,389</u>
Property and equipment, net	5,889	6,040
Total assets	<u>\$ 71,655</u>	<u>\$ 29,429</u>
Liabilities and Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,880	\$ 2,631
Deferred rent	84	84
Other current liabilities	177	204
Total current liabilities	<u>3,141</u>	<u>2,919</u>
Long-term liabilities:		
Royalty obligation payable	6,000	6,000
Notes payable and obligations under capital leases	1,136	1,178
Deferred rent	1,384	1,405
Total long-term liabilities	<u>8,520</u>	<u>8,583</u>
Total liabilities	<u>11,661</u>	<u>11,502</u>
Stockholder's equity:		
Preferred stock	--	--
Common stock	256	210
Additional paid-in capital, net	172,469	122,514
Deficit accumulated during the development stage	<u>(112,731)</u>	<u>(104,797)</u>
Total NewLink Genetics stockholders' equity	<u>59,994</u>	<u>17,927</u>
Total equity	<u>59,994</u>	<u>17,927</u>
Commitments	--	--
Total liabilities and equity	<u>\$ 71,655</u>	<u>\$ 29,429</u>

Contact:  
Gordon Link

Chief Financial Officer  
515-598-2925  
[glink@linkp.com](mailto:glink@linkp.com)

Source: NewLink Genetics Corporation

News Provided by Acquire Media