NewLink Genetics Announces Clinical Plan, Reports Second Quarter 2018 Financial Results and Revises Cash Guidance

July 31, 2018

Management to Host Conference Call Today at 4:30 p.m. ET

AMES, Iowa, July 31, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced its clinical plan and strategy, reported consolidated financial results for the second quarter of 2018, and revised its cash guidance.

Update on Clinical Programs

In early April, the Company announced a review of its clinical programs involving its lead immuno-oncology candidate, indoximod. This extensive review included an evaluation of available data from clinical trials sponsored by other companies, potential combination therapies with indoximod, and unmet medical need. Based on these key criteria, NewLink Genetics has focused its indoximod clinical programs on recurrent pediatric brain tumors, front-line treatment of diffuse intrinsic pontine glioma (DIPG), and front-line treatment of acute myeloid leukemia (AML). In addition, the company will continue to advance NLG802, the prodrug of indoximod with significantly higher pharmacokinetic exposure seen in preclinical research.

"Indoximod's unique mechanism of action has shown promising activity against multiple cancers and in combination with checkpoint inhibitors, radiation, chemotherapy, and vaccines," said Dr. Charles J. Link, Jr., MD, Chairman and Chief Executive Officer. "We intend to focus on near-term opportunities where additional data can validate the importance of indoximod in areas of high unmet need."

Recent Key Presentations

- Presented abstract 10973 entitled, *Front-line therapy of DIPG using the IDO pathway inhibitor indoximod in combination with radiation and chemotherapy,* during a plenary session at the American Association of Cancer Research (AACR) 2018 Annual Meeting in April, reporting on six newly diagnosed DIPG patients all of whom had completed induction radio-immunotherapy. Treatment was well tolerated with symptomatic improvement in all 6 patients. Site-reported radiographic review indicated near resolution of tumor in one patient at the end of radiotherapy and observable improvement in 5 out of 6 patients overall. A seventh patient with progressive DIPG received reirradiation combined with indoximod, which was well tolerated with symptomatic improvement and objective tumor reduction per site-reported assessment on post-treatment MRI.
- Presented abstract 3753 entitled, *Indoximod modulates AhR-driven transcription of genes that control immune function,* at the 2018 AACR Annual Meeting in April. Reported data show indoximod reverses the effects of low tryptophan by increasing proliferation of effector T cells, directly reprograms T regulatory cells into helper T cells and also downregulates IDO expression in dendritic cells, further supporting indoximod's differentiated mechanism of action.
- Presented abstract 9512 entitled, *Phase 2 trial of the IDO pathway inhibitor indoximod plus checkpoint inhibition for the treatment of patients with advanced melanoma,* at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting in June, demonstrating an Overall Response Rate (ORR) of 55.7% and a Complete Response (CR) of 18.6% which compares favorably to historical PD-1 monotherapy data.
- Presented abstract 4015 entitled, *Phase 2 trial of the IDO pathway inhibitor indoximod plus gemcitabine / nab-paclitaxel for the treatment of patients with metastatic pancreas cancer,* at the 2018 ASCO Annual Meeting in June, demonstrating a median Overall Survival (mOS) of 10.9 months and an Overall Response Rate (ORR) of 46.1%. The combination demonstrated potentially promising activity that correlated with a measurable immune response.
- Presented a poster entitled, *Radio-immunotherapy using the IDO pathway inhibitor indoximod for children with newly-diagnosed DIPG* at the International Symposium of Pediatric Neuro-Oncology (ISPNO) 2018 Annual Meeting in July. The updated Phase 1 data showed that all (10/10) front-line treatment DIPG patients, including the 6 patients previously presented at 2018 AACR Annual Meeting, demonstrated initial symptomatic improvement, and eight of ten had completed radiation, with the remaining 2 of 10 patients continuing radiotherapy. Currently, 9/10 patients remain on study, with the longest time on study of 8.5 months at the time of the report.

Anticipated Near-Term Milestones

- 2H 2018: Updated results from Phase 1b trial of indoximod plus standard-of-care chemotherapy for patients with newly diagnosed AML expected to be presented
- 2H 2018: Initial Phase 1 data from NLG802 expected to be presented
- 1H 2019: Updated results from Phase 1 trial of indoximod plus radio-chemotherapy for pediatric patients with recurrent malignant brain tumors including initial survival data expected to be presented

Organizational Changes

The company has completed an organizational realignment that will support these clinical development efforts within its current financial capacity, substantially cut future expenses, and extend its cash runway into the second half of 2021.

The organizational changes include a reduction in headcount of approximately 30%, and include the following changes to senior leadership, effective immediately:

- Jack Henneman has been appointed Chief Administrative Officer for a transition period to end with his retirement from NewLink in November 2018
- Carl Langren has been promoted to Chief Financial Officer
- Lori Lawley has been promoted to Vice President, Finance and Controller
- Brad Powers has been promoted to General Counsel

“We are grateful for the service and contributions made by Jack and all of those who have been a part of the NewLink team. This necessary transition is difficult for our company and our people, and we don’t take these changes lightly. That said, our company will focus its energies on clinical programs in the indications where patients are in the most need and with the best opportunity for clinical success,” said Nicholas Vahanian, MD, President.

Revised Cash Guidance

As a result of these measures, the company anticipates its current cash runway to extend into the second half of 2021, excluding any additional financings, proceeds from strategic alliances, the potential receipt of the priority review voucher, or expenditures related to external opportunities. The Company expects to use approximately $10 million per quarter after completing the restructuring.

Financial Results for the Three-Month Period Ended June 30, 2018

Cash Position: NewLink Genetics ended the quarter on June 30, 2018, with cash and cash equivalents totaling $137.1 million compared to $158.7 million for the year ending December 31, 2017.

R&D Expenses: Research and development expenses for the second quarter of 2018 were $12.1 million, a decrease of $6.1 million from $18.2 million for the same period in 2017. The decrease was due primarily to a decrease of $5.6 million in contract research and manufacturing spend, a decrease of $1.1 million in personnel-related and stock compensation expense, a $311,000 decrease in supplies, offset by an increase of $741,000 in clinical trial expense and an increase of $128,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses for the second quarter of 2018 were $7.9 million, a decrease of $1.0 million from $8.9 million for the same period in 2017. The decrease was due to a decrease of $313,000 of legal and consulting expense, a decrease of $787,000 in personnel-related and stock compensation expense offset by an increase of $182,000 in supplies and other expense.

Net Loss: NewLink Genetics reported a net loss of $17.3 million or ($0.47) per diluted share for the second quarter of 2018 compared to a net loss of $16.7 million or ($0.57) per diluted share for the second quarter of 2017.

NewLink Genetics ended the quarter with 37,198,100 shares outstanding.

Conference Call and Webcast Details

The Company has scheduled a conference call and webcast for 4:30 p.m. ET today to discuss the results and to give an update on clinical and business development activities. NewLink Genetics' senior management team will host the 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 conference 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 conference call will be webcast live and a link to the webcast can be accessed through the NewLink Genetics website at www.NewLinkGenetics.com in the "Investors & Media" section under "Events and Presentations" or by clicking here. To ensure a timely connection, it is recommended that users register at least 10 minutes prior to the scheduled webcast. 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 4478527. The replay will be available for two weeks from the date of the call.

About Indoximod

Indoximod is an investigational, orally available small molecule targeting the IDO pathway. The IDO pathway is a key immuno-oncology target, suppressing immune response and allowing for immune escape by degrading tryptophan with the resultant production of kynurenine. We hypothesize that immune activation using indoximod based combination immunotherapy can allow responsiveness to chemotherapy and radiation in patients who may otherwise be refractory or have limited benefit. The immuno-stimulatory effects of indoximod impact four main cell types: CD8+ T cells, CD4+ T helper cells, T regulatory cells, and dendritic cells. Indoximod reverses the effects of low tryptophan by increasing the proliferation of CD8+ effector T cells, drives differentiation into CD4+ T helper cells rather than regulatory T cells, and downregulates IDO expression in dendritic cells. Indoximod is being evaluated in combination with treatment regimens including chemotherapy, radiation, checkpoint blockade and cancer vaccines across multiple indications including recurrent pediatric brain tumors, DIPG, and AML.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on discovering, developing and commercializing novel immuno-oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are designed to harness multiple components of the immune system to combat cancer. For more information, please visit www.newlinkgenetics.com and follow us on Twitter @NLNKGenetics.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "guidance," "upcoming," "will," "plan," “intend,” "anticipate," "approximate," "expect," 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 2018; results of its clinical trials for product candidates; its timing of release of 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; the effects of its

organizational realignment; 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, 2017 and other reports filed with the U.S. Securities and Exchange Commission (SEC). 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.

Investor Contact:

Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

Media Contact:

Sharon Correia
VP, Integrated Communications
LaVoieHealthScience
617-374-8800, ext. 105
scorreia@lavoiehealthscience.com

Source: NewLink Genetics Corporation

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,	
	2018	**2017**	**2018**	**2017**
Grant revenue	$ 1,884	$ 10,314	$ 11,268	$ 12,900
Licensing and collaboration revenue	368	56	884	231
Total operating revenues	2,252	10,370	12,152	13,131
Operating expenses:				
Research and development	12,088	18,200	32,402	33,925
General and administrative	7,912	8,897	16,204	17,131
Total operating expenses	20,000	27,097	48,606	51,056
Loss from operations	(17,748)	(16,727)	(36,454)	(37,925)
Other income and expense:				
Miscellaneous income (expense)	10	(109)	34	(113)
Interest income	461	117	846	202
Interest expense	(36)	(7)	(49)	(113)
Other income (expense), net	435	1	831	(24)
Net loss before taxes	(17,313)	(16,726)	(35,623)	(37,949)
Income tax benefit	—	—	—	310
Net loss	$ (17,313)	$ (16,726)	$ (35,623)	$ (37,639)
Basic and diluted loss per share	$ (0.47)	$ (0.57)	$ (0.96)	$ (1.29)
Basic and diluted average shares outstanding	37,165,529	29,225,386	37,160,334	29,219,469

NewLink Genetics Corporation
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	Year Ended June 30, 2018	**December 31, 2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 137,066	$ 158,708

Prepaid expenses and other current assets	5,243	6,226
Income tax receivable	360	356
Other receivables	817	10,176
Total current assets	143,486	175,466
Property and equipment, net	4,387	5,091
Income tax receivable	140	$ 140
Total non-current assets	4,527	$ 5,231
Total assets	$ 148,013	$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,334	$ 9,256
Accrued expenses	8,527	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	87	92
Current portion of notes payable and obligations under capital leases	93	160
Total current liabilities	16,041	22,031
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	74	111
Deferred rent	952	998
Total long-term liabilities	7,026	7,109
Total liabilities	23,067	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares - 5,000,000 at June 30, 2018 and December 31, 2017; issued and outstanding shares - 0 at June 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at June 30, 2018 and December 31, 2017; issued 37,285,745 and 37,168,122 at June 30, 2018 and December 31, 2017, respectively, and outstanding 37,198,100 and 37,109,556 at June 30, 2018 and December 31, 2017, respectively	373	372
Additional paid-in capital	399,018	389,786
Treasury stock, at cost: 87,645 and 58,566 shares at June 30, 2018 and December 31, 2017, respectively	(1,405)	(1,142)
Accumulated deficit	(273,040)	(237,459)
Total stockholders' equity	124,946	151,557
Total liabilities and stockholders' equity	$ 148,013	$ 180,697

Primary Logo

Source: NewLink Genetics Corporation