NewLink Genetics Reports Third Quarter 2018 Financial Results and Announces Abstracts to Be Presented at Upcoming Medical Meetings

November 1, 2018

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

AMES, Iowa, Nov. 01, 2018 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today reported consolidated financial results for the third quarter 2018 and reviewed recent highlights and upcoming milestones.

"NewLink Genetics continues to produce encouraging data supporting indoximod in targeted cancer indications. We remain confident in the advancement of our clinical programs as we strive to develop novel therapies addressing areas of great unmet need," said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. "We look forward to presenting data at SITC and ASH this fall."

Data to be Presented at Upcoming Medical Meetings

- Abstract accepted for oral presentation at the ASH Annual Meeting, December 1-4, 2018
  - Abstract 332: *Indoximod combined with standard induction chemotherapy is well tolerated and induces a high rate of complete remission with MRD-negativity in patients with newly diagnosed AML: results from a Phase 1 trial,* Emadi, A., et al. - to be presented during the oral session, 616 entitled "Acute Myeloid Leukemia: Novel Therapy, excluding Transplantation: Combination Therapy" Sunday, Dec 2, 2018, 9:30- 11:00 AM PT. Data indicate that a high percentage of newly diagnosed AML patients treated with indoximod plus standard-of-care (SOC) chemotherapy achieved complete response (CR) and showed no evidence of minimal residual disease (were MRD-negative). Indoximod was well tolerated.
- Abstracts accepted for poster presentation at the SITC Annual Meeting, November 7-11, 2018
  - Abstract 11213: *A phase 1a clinical trial of NLG802, a prodrug of indoximod with enhanced pharmacokinetic properties*, Rixe, O., et al. (Poster #P331)
  - Abstract 10294: *The immunogenomic impact of indoximod on the tumor microenvironment of melanoma patients*, Yu, J., et al. (Poster #P142)
  - Abstract 10304: *Effects of indoximod plus gemcitabine/nab-paclitaxel on tumor microenvironment of patients with metastatic pancreatic cancer,* Yu, J., et al. (Poster #P706)
  - Posters are being presented on Friday, November 9th, and Saturday, November 10th, from 8 AM to 8 PM, in Exhibition Hall E of the Walter E. Washington Convention Center.

Outlook for 2019

- Updated results from Phase 1 trial of indoximod plus radiotherapy for pediatric patients with recurrent malignant brain tumors including initial survival data expected to be presented 1H 2019
- Updated data from Phase 1 trial of indoximod plus radiotherapy in DIPG anticipated in 2019
- Data from Phase 2 trial of NLG207 (CRLX101), a nanoparticle formulation of the topoisomerase 1 inhibitor, camptothecin, plus paclitaxel in recurrent ovarian cancer anticipated in 2019

Clinical Update

NewLink Genetics continues its clinical trials of indoximod in combination therapies for adult patients with newly diagnosed AML, pediatric patients with recurrent brain tumors, and pediatric patients with newly diagnosed DIPG. These targeted indications are those with unmet need where indoximod has produced encouraging early data and where standard-of-care therapy has not changed significantly for decades.

A Phase 2 study evaluating NLG207, a nanoparticle formulation of the topoisomerase 1 inhibitor camptothecin, in combination with paclitaxel for patients with recurrent ovarian cancer is complete, and data analysis is underway. NLG207 is an asset acquired from Cerulean Pharma Inc. in 2017. This trial is being conducted in conjunction with the Gynecological Oncology Group.

Board Changes

Paolo Pucci has resigned his position as a Director on NewLink Genetics' Board effective October 31, 2018 due to the increasing responsibilities associated with his current position as CEO of ArQule, Inc. and current guidelines of proxy advisors regarding the number of directorships to be held by a CEO. With Mr. Pucci's departure, NewLink's Board will consist of seven directors.

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

Cash Position: NewLink Genetics ended the quarter on September 30, 2018, with cash and cash equivalents totaling $122.1 million compared to $158.7 million for the year ending December 31, 2017.

R&D Expenses: Research and development expenses for the third quarter of 2018 were $7.6 million, a decrease of $10.9 million from $18.5 million for the same period in 2017. The decrease was due to reductions of $7.3 million in contract research and manufacturing spend, $2.5 million in clinical trial expense, $570,000 in personnel-related and stock compensation expense, $560,000 in supplies and licensing, and $100,000 in restructuring costs. These reductions were offset by an increase of $70,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses for the third quarter of 2018 were $7.6 million, a decrease of $320,000 from $7.9 million for the same period in 2017. The decrease was due to reductions of $300,000 in restructuring costs, $240,000 in legal and consulting expenses, and

$10,000 in personnel-related and stock compensation expense. These reductions were offset by an increase of $230,000 in supplies and other expense.

Net Loss: NewLink Genetics reported a net loss of $7.4 million or ($0.20) per diluted share for the third quarter of 2018 compared to a net loss of $20.6 million or ($0.69) per diluted share for the third quarter of 2017.

NewLink Genetics ended the quarter with 37,216,892 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) 235-8286 (U.S.) or (267) 753-2161 (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 1753698. 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. Indoximod reverses the immunosuppressive effects of low tryptophan and high kynurenine through mechanisms that include modulation of the AhR-driven transcription of genes that control immune function. This results in increased proliferation of effector T cells, increased differentiation into helper T cells rather than regulatory T cells, and downregulation of 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 developing 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 & Media Contact:

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

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,	
	2018	**2017**	**2018**	**2017**
Grant revenue	$ —	$ 5,379	$ 11,268	$ 18,279
Licensing and collaboration revenue	120	103	1,004	334

Total operating revenues	120	5,482	12,272	18,613
Operating expenses:				
Research and development	7,570	18,480	39,972	52,405
General and administrative	7,588	7,907	23,792	25,038
Total operating expenses	15,158	26,387	63,764	77,443
Loss from operations	(15,038)	(20,905)	(51,492)	(58,830)
Other income and expense:				
Miscellaneous income (expense)	(18)	12	16	(101)
Interest income	664	151	1,510	353
Interest expense	(2)	(3)	(51)	(116)
Other income (expense), net	644	160	1,475	136
Net loss before taxes	(14,394)	(20,745)	(50,017)	(58,694)
Income tax benefit	6,991	119	6,991	429
Net loss	$ (7,403)	$ (20,626)	$ (43,026)	$ (58,265)
Basic and diluted loss per share	$ (0.20)	$ (0.69)	$ (1.16)	$ (1.98)
Basic and diluted average shares outstanding	37,214,363	29,939,823	37,178,542	29,462,226

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

	Year Ended September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 122,061	$ 158,708
Prepaid expenses and other current assets	4,920	6,226
Income tax receivable	7,398	356
Other receivables	700	10,176
Total current assets	135,079	175,466
Property and equipment, net	4,096	5,091
Income tax receivable	140	$ 140
Total non-current assets	4,236	$ 5,231
Total assets	$ 139,315	$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,238	$ 9,256
Accrued expenses	8,736	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	84	92
Current portion of notes payable and obligations under capital leases	74	160
Total current liabilities	10,132	22,031
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	59	111
Deferred rent	929	998
Total long-term liabilities	6,988	7,109
Total liabilities	17,120	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares - 5,000,000 at September 30, 2018 and December 31, 2017; issued and outstanding shares - 0 at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at September 30, 2018 and December 31, 2017; issued 37,305,626 and 37,168,122 at September 30, 2018 and December 31, 2017, respectively, and outstanding 37,216,892 and 37,109,556 at September 30, 2018 and December 31, 2017, respectively	373	372
Additional paid-in capital	399,018	389,786
Treasury stock, at cost: 88,734 and 58,566 shares at September 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	$ 142,066	$ 180,697

Source: NewLink Genetics Corporation