NewLink Genetics Reports Fourth Quarter, Year-End 2018 Financial Results and Provides Update for Clinical Programs

February 27, 2019

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

AMES, Iowa, Feb. 27, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today reported consolidated financial results for the fourth quarter and year ended 2018, as well as progress in its clinical development programs. The Company also outlined key 2019 priorities related to its clinical pipeline.

"In 2018, we published further clinical results on indoximod that suggest it has significant activity in combination therapy for a variety of cancer indications," said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer. "As we enter 2019 with a strong cash position, our intention is to focus on developing the best potential registration strategy for bringing indoximod forward and further developing our pipeline assets, especially NLG207. We would like to thank the investigators and patients who support our clinical trials year after year, and we remain committed to your care."

Anticipated 2019 Outlook

- Updated results on the cohort of patients with newly diagnosed diffuse intrinsic pontine glioma (DIPG), from the efficacy portion of a Phase 1b study of indoximod for the treatment of pediatric patients with recurrent malignant brain tumors, are anticipated in 2019
- Results from a Phase 2 study of NLG207 (formerly CRLX101), a nanoparticle formulation of the topoisomerase 1 inhibitor, camptothecin, conducted by the Gynecological Oncology Group (GOG) for patients with recurrent ovarian cancer, has been accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting 2019, at the Georgia World Conference Center, in Atlanta, March 29 - April 3, 2019
- Updated results from a Phase 1 study of NLG802, a prodrug of indoximod with enhanced pharmacokinetic properties, are anticipated in 2019
- Updated results from a Phase 1b study of indoximod for pediatric patients with recurrent malignant brain tumors are anticipated in 2019
- Completion by Merck of the rolling Biologics License Application (BLA) filing for V920 (rVSVΔG-ZEBOV-GP), our partnered Ebola vaccine candidate, is expected in 2019

2018 Highlights

- Presented Phase 1 results of indoximod plus front-line radiation and maintenance chemotherapy for the treatment of pediatric patients with newly diagnosed DIPG at the American Association of Clinical Research (AACR) Annual Meeting, April 2018, and updated Phase 1 results at the International Symposium of Pediatric Neuro-Oncology (ISPNO) Annual Meeting, July 2018, showing symptomatic improvement and marked radiographic improvement in DIPG patients.
- Presented updated Phase 1 results for indoximod plus standard of care chemotherapy for younger, healthy patients with newly diagnosed acute myeloid leukemia (AML) in an oral session at the 60thAmerican Society of Hematology (ASH) Annual Meeting, December 2018
- Presented final results from two Phase 2 studies of indoximod at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting with results for indoximod plus checkpoint inhibition in advanced melanoma which we believe showed encouraging overall and complete response rates which compared favorably to historical PD-1 monotherapy results and results for indoximod plus gemcitabine / nab-paclitaxel in metastatic pancreatic cancer demonstrating potentially promising activity that correlated with a measurable immune response
- At the Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting, we presented correlative immunologic assay results from biopsies obtained during both the advanced melanoma and the metastatic pancreatic cancer trials previously presented at ASCO 2018, illustrating indoximod's impact on the tumor microenvironment as well as first-in-human results showing significantly enhanced pharmacokinetic properties of our indoximod prodrug, NLG802
- November 13, 2018, our partner, Merck, announced that it had begun the rolling submission of licensure application for Ebola vaccine, V920 (rVSVΔG-ZEBOV-GP), to the FDA

Financial Results

Cash Position: NewLink Genetics ended the year on December 31, 2018, with cash and cash equivalents totaling $120.7 million compared

to $158.7 million for the year ending December 31, 2017. The Company projects its cash position is sufficient to fund planned operations through the end of 2021.

R&D Expenses: Research and development expenses were $5.7 million and $45.7 million in the fourth quarter and year ended December 31, 2018 compared to $17.5 million and $69.9 million during the comparable periods in 2017. The decrease year-over-year was due primarily to a $15.2 million reduction in contract research and manufacturing expense, $3.0 million in personnel-related expense, $3.3 million in supplies and equipment, $1.8 million in clinical trial costs, $1.3 million in technology and licensing, and reduction in restructuring expenses of $100,000, offset by a $500,000 increase in consulting and other costs.

G&A Expenses: General and administrative expenses in the fourth quarter and year ended December 31, 2018 were $5.4 million and $29.2 million compared to $6.7 million and $31.7 million during the comparable periods in 2017. The year-over-year decrease of $2.5 million was due to a reduction of $2.5 million in personnel-related spending, $550,000 reduction in consulting and other costs, reduction in restructuring expenses of $300,000, offset by an $850,000 increase in supplies and other expenses.

Net Loss: NewLink Genetics reported a net loss of $10.6 million or a loss of $0.28 per diluted share for the fourth quarter of 2018 and a net loss of $53.6 million or a loss of $1.44 per diluted share for the year ended December 31, 2018, compared to a net loss of $13.7 million or $0.37 per diluted share for the fourth quarter of 2017 and a net loss of $72.0 million or $2.30 per diluted share for the year ended December 31, 2017.

NewLink Genetics ended 2018 with 37,251,220 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 through this link https://edge.media-server.com/m6/p/dqq32drc. To ensure a timely connection, it is recommended that users register at least 15 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 1279102. 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 NLG207

NLG207 (formerly CRLX101) is an investigational nanoparticle-drug conjugate (NDC) composed of a cyclodextrin-based polymer backbone conjugated to camptothecin, a topoisomerase-1 inhibitor. NDCs enhance drug delivery to tumors where gradual payload release inside cancer cells augments antitumor activity while reducing toxicity. Topoisomerase 1 inhibitors are a class of drugs that modify DNA damage responses in cancer cells. NewLink Genetics is evaluating NLG207 in a series of clinical trials in advanced refractory ovarian cancer patients.

About NewLink Genetics Corporation

NewLink Genetics is a clinical stage biopharmaceutical company focusing on developing novel oncology product candidates to improve the lives of patients with cancer. NewLink Genetics' IDO pathway inhibitors are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. NewLink Genetics' nanoparticle drug candidate, NLG207, conjugated to camptothecin, a topoisomerase 1 inhibitor is under development to combat refractory malignancies. 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 Genetics 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 2019 and beyond; results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to execution of clinical trials; 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; 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 & Media Contact:
Lisa Miller
Director of Investor Relations
NewLink Genetics
515-598-2555
lmiller@linkp.com

NewLink Genetics Corporation
Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	**2017**	**2018**	**2017**
Grant revenue	$ —	$ 10,042	$ 11,268	$ 28,321
Licensing and collaboration revenue	202	56	1,206	390
Total operating revenues	202	10,098	12,474	28,711
Operating expenses:				
Research and development	5,721	17,461	45,694	69,866
General and administrative	5,427	6,688	29,218	31,726
Total operating expenses	11,148	24,149	74,912	101,592
Loss from operations	(10,946)	(14,051)	(62,438)	(72,881)
Other income and expense:				
Miscellaneous expense	(118)	(24)	(102)	(126)
Interest income	519	263	2,029	616
Interest expense	(2)	(4)	(52)	(119)
Other income, net	399	235	1,875	371
Net loss before taxes	(10,547)	(13,816)	(60,563)	(72,510)
Income tax (expense) benefit	(22)	130	6,968	559
Net loss	$ (10,569)	$ (13,686)	$ (53,595)	$ (71,951)
Basic and diluted loss per share	$ (0.28)	$ (0.37)	$ (1.44)	$ (2.30)
Basic and diluted average shares outstanding	37,229,006	36,770,490	37,191,262	31,304,309

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

	Year Ended December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 120,738	$ 158,708
Prepaid expenses and other current assets	5,536	6,226
Income tax receivable	339	356
Other receivables	459	10,176
Total current assets	127,072	175,466
Property and equipment, net	3,727	5,091
Income tax receivable	140	$ 140
Total non-current assets	3,867	$ 5,231
Total assets	$ 130,939	$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 555	$ 9,256
Accrued expenses	8,139	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	92	92
Current portion of notes payable and obligations under capital leases	61	160
Total current liabilities	8,847	22,031
Long-term liabilities:		

Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	43	111
Deferred rent	906	998
Total long-term liabilities	6,949	7,109
Total liabilities	15,796	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares - 5,000,000 at December 31, 2018 and 2017; issued and outstanding shares - 0 at December 31, 2018 and 2017	—	—
Common stock, $0.01 par value: Authorized shares - 75,000,000 at December 31, 2018 and 2017; issued 37,343,547 and 37,168,122 at December 31, 2018 and 2017, respectively, and outstanding 37,251,220 and 37,109,556 at December 31, 2018 and 2017, respectively	373	372
Additional paid-in capital	407,199	389,786
Treasury stock, at cost: 92,327 and 58,566 shares at December 31, 2018 and 2017, respectively	(1,417)	(1,142)
Accumulated deficit	(291,012)	(237,459)
Total stockholders' equity	115,143	151,557
Total liabilities and stockholders' equity	$ 130,939	$ 180,697

Source: NewLink Genetics Corporation