NewLink Genetics Reports First Quarter 2019 Financial Results and Provides Clinical Activities Update

May 8, 2019

- Management to host conference call today at 4:30 p.m. ET

AMES, Iowa, May 08, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) today announced financial results for the first quarter ended March 31, 2019 and provided an update on clinical activities.

“We continued to make progress across our clinical programs this year. We look forward to presenting additional encouraging data later this month on NLG802. We were also pleased to present Phase 2 results for NLG207 in combination with weekly paclitaxel for patients with recurrent ovarian cancer at AACR, which demonstrated an encouraging safety profile supporting the potential of NLG207 as a best-in-class topoisomerase 1 inhibitor for those women who had received multiple lines of therapy,” said Charles J. Link, Jr, MD, Chairman and Chief Executive Officer of NewLink Genetics. “With a strong cash position of $113.2 million at the end of the quarter, we are well positioned to continue moving our clinical programs forward, and we anticipate sharing additional data from our pipeline in the coming quarters as we prioritize clinical development programs with a focus on indications with high unmet need and a potential path forward to registration.”

Clinical Update and Anticipated Upcoming Milestones

The Company has had an abstract accepted, and plans to present updated data from a Phase 1 dose-escalation study of NLG802, a prodrug of indoximod, at the Immuno-Oncology 2019 2nd World Congress in Barcelona, Spain, May 23-24, 2019.

The Phase 2 study of NLG207 (formerly CRLX101) in combination with weekly paclitaxel for patients with recurrent ovarian cancer, conducted in conjunction with The GOG Foundation, is complete. The Company recently presented results from this study at the American Association for Cancer Research (AACR) Annual Meeting 2019, and we are evaluating NLG207 as a potential therapeutic in gynecologic malignancies.

Updated results from the cohort of patients with DIPG in the efficacy portion of a Phase 1b study of indoximod for the treatment of pediatric patients with recurrent malignant brain tumors are anticipated later in 2019.

In reference to NewLink Genetics’ partnered Ebola vaccine candidate, Merck recently announced that the European Medicines Agency (EMA) has accepted the Marketing Authorization Application for this vaccine, V920 (rVSVΔG-ZEBOV-GP). In addition, completion of the rolling Biologics License Application (BLA) filing with the FDA by Merck is anticipated in 2019. Should this vaccine be approved by the FDA, a Priority Review Voucher (PRV) would be issued, in which NewLink Genetics owns a substantial financial interest.

Financial Results for the Three-Month Period Ended March 31, 2019

Cash Position: NewLink Genetics ended the quarter on March 31, 2019, with cash and cash equivalents totaling $113.2 million compared to $120.7 millionDecember 31, 2018. The Company projects its cash position is sufficient to fund planned operations through the end of 2021.

R&D Expenses: Research and development expenses for the first quarter of 2019 were $5.2 million, a decrease of $15.1 million from $20.3 million for the same period in 2018. The decrease was primarily due to reductions of $9.9 million in contract research and manufacturing spend, $2.2 million in personnel-related and stock compensation expense, $2.1 million in clinical trial expense, $500,000 in supplies and licensing, and $400,000 in legal and consulting expense.

G&A Expenses: General and administrative expenses in the first quarter of 2019 were $5.6 million, a decrease of $2.7 million from $8.3 million for the same period in 2018. The decrease was due primarily to reductions of $2.1 million in personnel-related and stock compensation expense, $605,000 in legal and consulting expense, offset by an increase of $72,000 in supplies and travel expense.

Net Loss: NewLink Genetics reported a net loss of $10.0 million or ($0.27) per diluted share for the first quarter of 2019 compared to a net loss of $18.3 million or ($0.49) per diluted share for the first quarter of 2018.

NewLink Genetics ended Q1 2019 with 37,276,102 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 its financial results and to give an update on clinical and business development activities. There will also be a question and answer session following management’s prepared remarks.

Access to the live conference call is available five minutes prior to the start of the call by dialing (855) 469-0612 (U.S.) or (484) 756-4268 (international) and using the conference ID 8457627. 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 conference ID 8457627. 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 DIPG, recurrent pediatric brain tumors, and AML.

About NLG802

NLG802 is an investigational, orally available prodrug of indoximod, a small molecule targeting the IDO Pathway. The IDO Pathway is one of the key immuno-oncology targets involved in regulating the tumor microenvironment and immune escape. NewLink Genetics is currently evaluating NLG802 in a Phase 1 dose-escalation clinical trial in cancer patients to assess the safety and pharmacokinetics of NLG802.

About NLG207

NLG207 (formerly CRLX101) is an investigational nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked 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, indoximod and its prodrug, NLG802, are immuno-oncology drug candidates designed to harness multiple components of the immune system to combat cancer. NewLink Genetics' drug candidate, NLG207, a nanoparticle formulation of 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, 2018 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.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating Revenues:		
Grant revenue	$ —	$ 9,384
Licensing and collaboration revenue	106	516
Total operating revenues	106	9,900
Operating expenses:		
Research and development	5,203	20,314
General and administrative	5,567	8,292
Total operating expenses	10,770	28,606
Loss from operations	(10,664)	(18,706)
Other income and expense:		
Miscellaneous income	5	24
Interest income	624	385
Interest expense	(1)	(13)
Other income, net	628	396
Net loss before taxes	(10,036)	(18,310)
Income tax benefit	—	—

Net loss	$ (10,036)	$ (18,310)
Basic and diluted loss per share	$ (0.27)	$ (0.49)
Basic and diluted average shares outstanding	37,275,459	37,155,082

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 113,184	$ 120,738
Prepaid expenses and other current assets	4,447	5,536
Income tax receivable	341	339
Other receivables	305	459
Total current assets	118,277	127,072
Property and equipment, net	3,520	3,727
Right-of-use asset	7,334	$ —
Income tax receivable	140	$ 140
Total non-current assets	10,994	$ 3,867
Total assets	$ 129,271	$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 896	$ 555
Accrued expenses	6,950	8,139
Current portion of deferred rent	—	92
Current portion of lease liability	963	
Current portion of notes payable	63	61
Total current liabilities	8,872	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable	27	43
Lease Liability	7,353	
Deferred rent	—	906
Total long-term liabilities	13,380	6,949
Total liabilities	22,252	15,796
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2019 and December 31, 2018; issued and outstanding shares — 0 at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2019 and December 31, 2018; issued 37,387,876 and 37,343,547 at March 31, 2019 and December 31, 2018, respectively, and outstanding 37,276,102 and 37,251,220 at March 31, 2019 and December 31, 2018, respectively	373	373
Additional paid-in capital	409,143	407,199
Treasury stock, at cost: 111,774 and 92,327 shares at March 31, 2019 and December 31, 2018, respectively	(1,449)	(1,417)
Accumulated deficit	(301,048)	(291,012)
Total stockholders' equity	107,019	115,143
Total liabilities and stockholders' equity	$ 129,271	$ 130,939

Source: NewLink Genetics Corporation