

# **NewLink Genetics and Lumos Pharma Enter into Merger Agreement to Form Biopharmaceutical Company Focused on Developing Therapies to Treat Rare Diseases**

September 30, 2019

- Combined company to assume the name, Lumos Pharma, Inc. and is expected to be led by Richard J. Hawkins, current CEO of Lumos Pharma --**
- Lumos asset, LUM-201, represents first oral therapeutic candidate for pediatric growth hormone deficiency (PGHD) with planned Phase 2b expected to begin in mid-2020 --**
- Lumos Pharma stockholders, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates, Santé Ventures, and UCB have approved the transaction --**
- Companies to host investor call tomorrow, October 1<sup>st</sup>, at 8:30 a.m. EDT --**

AUSTIN, Texas and AMES, Iowa, Sept. 30, 2019 (GLOBE NEWSWIRE) -- NewLink Genetics Corporation (NASDAQ:NLNK) and Lumos Pharma, Inc., a private clinical stage biopharmaceutical company focused on development and commercialization of therapeutics for rare diseases, today announced that the companies have entered into a definitive merger agreement. Under the terms of the agreement, NewLink will issue Lumos Pharma stockholders NewLink common stock in exchange for their shares in Lumos such that Lumos Pharma stockholders will own approximately 50% of NewLink. Immediately following the closing of the merger, Lumos Pharma will become a wholly-owned subsidiary of NewLink, and NewLink will be renamed "Lumos Pharma, Inc." and will trade on Nasdaq under the symbol "LUMO." The combined company is expected to have offices in Austin, TX and Ames, IA. The Boards of Directors of both companies have approved the transaction. Major stockholders of Lumos Pharma have also approved the transaction, and the largest stockholder of NewLink has signed a support agreement in favor of the merger transaction. The transaction is anticipated to close in the first quarter of 2020.

The proposed merger would create a biopharmaceutical company focused initially on the development of Lumos Pharma's lead candidate, LUM-201 (ibutamoren), a potential oral therapy for pediatric growth hormone deficiency (PGHD) and other rare endocrine disorders. The merger would combine the Lumos management team's deep experience in rare diseases and endocrinology with NewLink's expertise in drug development and its solid financial position. This merger is expected to provide the financial support necessary to expedite the clinical development of LUM-201 for PGHD, for which the next step is the anticipated initiation of a Phase 2b clinical trial in mid-2020. The planned Phase 2b clinical trial will evaluate LUM-201 for children with PGHD compared to the current standard of care: daily injections of recombinant human growth hormone (rhGH).

"We believe this combined entity offers us a new, strategic position in the market and has the potential to create significant value to patients and our stockholders alike," said Eugene Kennedy, MD, Chief Medical Officer of NewLink. "Rick Hawkins and the other members of the Lumos senior management team bring longstanding experience in rare disease drug development and corporate management, which align ideally with our new strategic focus," he added.

"Our board and entire team are pleased to announce this exciting merger with NewLink," said Rick Hawkins, CEO of Lumos Pharma. "Working toward the development and commercialization of novel therapies for rare diseases remains the cornerstone of Lumos Pharma's strategy. As we advance LUM-201 for PGHD through later stages of clinical development, we believe there is an established regulatory path to approval and the opportunity for LUM-201 to become the world's first oral therapeutic for pediatric growth hormone deficiency. Other target indications for LUM-201 have potential for development, supporting expanded market opportunity for this drug candidate. With exciting prospects for the clinic, we are optimistic about what this combined company will achieve."

The market for PGHD is well-established and sizable, with current and anticipated therapies consisting of injectable treatments of rhGH or its derivatives. LUM-201 would potentially represent the first orally administered therapeutic for PGHD, with the aim to supplant a prolonged treatment regimen of frequent injections. LUM-201 is a growth hormone (GH) secretagogue, providing a differentiated mechanism of action to treat PGHD by increasing the amplitude of endogenous, pulsatile GH secretion. Related to LUM-201's mechanism of action, clinically-derived predictive enrichment markers (PEM) are planned to be employed to optimize the targeted patient population for future clinical trials and treatment. LUM-201 has orphan drug designation for the treatment of growth hormone deficiency in the U.S. and EU, as well as an issued U.S. patent which expires in 2036 and pending patent applications in other jurisdictions.

In addition, the combined company expects to evaluate other opportunities to acquire or in-license assets addressing rare diseases to grow its pipeline and expects to continue to evaluate NewLink's oncology portfolio to determine value creation opportunities.

## **Proposed Transaction Details**

Under the terms of the merger agreement, at the effective time of the merger, the outstanding shares of Lumos Pharma capital stock will be converted into the right to receive a number of newly issued shares of NewLink common stock at exchange ratios applicable to each series of capital stock. The conversion of all Lumos Pharma capital stock will result in former Lumos Pharma and NewLink stockholders each owning approximately 50% of the combined company's outstanding common stock. In conjunction with the transaction, the combined company plans to effect a reverse stock split.

The transaction has been approved by the Boards of Directors of both companies and the majority of Lumos Pharma stockholders, which include Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), and Santé Ventures. The largest stockholder of NewLink, Stine Seed Farm, Inc., has also pledged to support the agreement. The transaction is expected to close in the first quarter of 2020, subject to the satisfaction of customary closing conditions, including approval by the stockholders of NewLink Genetics.

NewLink is being advised by Stifel as financial advisor and Cooley LLP as legal counsel. Lumos Pharma is being advised by DLA Piper LLP (US) as legal counsel.

## **Management and Organization**

Following the merger, Richard J. Hawkins, current Chief Executive Officer of Lumos Pharma, is expected to become Chief Executive Officer of the

combined company. Additional management of the combined company is expected to include John McKew, PhD, Chief Scientific Officer of Lumos Pharma as Chief Scientific Officer of the combined company; Eugene Kennedy, MD, Chief Medical Officer of NewLink as Chief Medical Officer of the combined company; and Carl Langren, Chief Financial Officer of NewLink as Chief Financial Officer of the combined company. The Board of Directors is expected to be composed of three directors designated by NewLink, three directors designated by Lumos Pharma, and one director jointly designated by both companies. Upon closing of the transaction, the combined company will operate as Lumos Pharma, Inc. The company expects to have offices in Austin, Texas and Ames, Iowa.

Today, NewLink Genetics announced that Nicholas Vahanian, M.D. has chosen to retire from his position as President of the company and has also resigned from its Board of Directors; both effective Friday, September 27, 2019. Dr. Vahanian cofounded NewLink Genetics in 1999 and has served as President of the company since 2009 and as a member of its Board of Directors since 2015. Previously, he served as NewLink's Chief Medical Officer and Chief Operations Officer.

"Cofounding and leading NewLink these past 20 years has been a most rewarding experience particularly with the recent announcement that our partnered Ebola vaccine has been accepted for priority review by the FDA," said Nicholas Vahanian, M.D. "It has been remarkable to work with people who remain committed to keeping patients at the center of all that we do. I am grateful to my colleagues and our stockholders for this incredible chapter in my life and am excited about what lies ahead, both for me and for NewLink Genetics as the company works to consummate the proposed merger with Lumos Pharma."

Thomas A. Raffin, M.D., Lead Independent Director of NewLink Genetics commented, "NewLink Genetics is grateful to its cofounder, Nick Vahanian, for the insight and relentless energy he brought to the company throughout his tenure. The Board thanks Dr. Vahanian for these and many other contributions he has made to the company and wishes him well in his future endeavors."

On September 30, 2019, management commenced a restructuring plan in the context of the anticipated merger. This action is expected to be substantially completed by December 31, 2019. The objective of the restructuring is to reduce NewLink's operating expenses and align its personnel with the anticipated needs of NewLink following the merger.

Under the restructuring plan, NewLink will reduce its workforce by 28 employees (approximately 60%), including several members of management. NewLink expects that the workforce reduction and the change in the management team will decrease its cash payroll expense by approximately \$5.0-\$6.0 million annually.

In connection with the restructuring and the departure of Dr. Vahanian, NewLink estimates that it will incur aggregate restructuring charges of approximately \$4.5 million, which will be recorded in the third and fourth quarters of 2019, related to one-time termination severance payments and other employee-related costs, excluding any amounts related to stock-based compensation expense for the acceleration of stock options and the extension of post-termination stock option exercise periods. The charges that it expects to incur in connection with the workforce reduction is subject to a number of assumptions, and actual results may differ materially. NewLink may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction.

### **Financial Position and Operational Synergies**

In advance of the proposed merger, NewLink has commenced an organizational realignment to support the operational and strategic activities of the combined company upon close of the merger. The parties expect the combined company to have approximately \$80.0 million in cash as of December 31, 2019 (unaudited pro forma cash balance), which excludes cash reserved for restructuring and severance costs relating to the departures of NewLink executives and other employees. The combined company forecasts that the average cash spend per quarter in 2020 will be approximately \$6.5-\$7.5 million, excluding restructuring and severance costs, acquisitions, licensing or financing opportunities. This financial position is expected to be sufficient to support the combined company's planned clinical development program through the readout of its Phase 2b clinical trial of LUM-201. The combined company may receive additional, non-dilutive financing should the U.S. Food and Drug Administration (FDA) approve NewLink's partnered Ebola vaccine V920, triggering the issuance of a monetizable priority review voucher (PRV) in which NewLink has a substantial interest. On September 17, 2019, it was announced that the FDA has accepted the biologics license application (BLA) for Ebola vaccine V920 and the Prescription Drug User Fee Act (PDUFA), or target action date, is set for March 14, 2020.

### **Conference Call and Webcast Details**

The companies have scheduled a conference call and webcast for 8:30 a.m. EDT tomorrow, October 1<sup>st</sup>, to review the transaction. Access to the live conference call is available by dialing (855) 469-0612 (U.S.) or +1 (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 here at <https://edge.media-server.com/mmc/p/ko4geqtk>, through the NewLink Genetics website at [www.NewLinkGenetics.com](http://www.NewLinkGenetics.com) in the "Investors & Media" section under "Events and Presentations," or through the Lumos Pharma website at <https://lumos-pharma.com/> in the "News" section. 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 +1 (404) 537-3406 (international) and using the passcode 1287208. The replay will be available for 60 days from the date of the call.

### **Additional Information and Where to Find It**

In connection with the proposed transaction, NewLink Genetics will be filing documents with the SEC, including preliminary and definitive proxy statements relating to the proposed transaction. The definitive proxy statement will be mailed to NewLink Genetics' stockholders in connection with the proposed transaction. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at [www.sec.gov](http://www.sec.gov), on NewLink Genetics' website at [www.newlinkgenetics.com](http://www.newlinkgenetics.com) or by contacting NewLink Genetics' Investor Relations at 515-598-2555.

### **Participants in the Solicitation**

NewLink and Lumos Pharma and their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from NewLink stockholders in connection with the proposed transaction. Information about NewLink's directors and executive officers and their ownership of NewLink's securities is set forth in NewLink Genetics' proxy statement for its 2019 Annual Meeting of Stockholders, which was filed with the SEC on April 5, 2019, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of such filing. Other information regarding the proposed transaction, including information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the proxy statements described above and other relevant materials to be filed with the SEC when they become available. These documents are or will be available free of charge at the SEC's web site at [www.sec.gov](http://www.sec.gov) and from other sources indicated above.

#### **About Lumos Pharma**

Lumos Pharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of therapeutics for rare and neglected diseases. Lumos Pharma was founded and is led by a management team with longstanding experience in rare disease drug development and is funded by leading healthcare investors, including Deerfield Management, a fund managed by Blackstone Life Sciences, Roche Venture Fund, New Enterprise Associates (NEA), Santé Ventures, and UCB. Lumos Pharma's lead product candidate is LUM-201, an oral growth hormone stimulating therapeutic, is in late stage clinical development for the treatment of Pediatric Growth Hormone Deficiency (PGHD). If approved by the FDA, LUM-201 would provide an alternative to the injections that current PGHD patients endure for many years of treatment. LUM-201 has received Orphan Drug Designation in both the US and EU. For more information, please visit [www.lumos-pharma.com](http://www.lumos-pharma.com).

#### **About NewLink Genetics Corporation**

NewLink Genetics is a clinical stage biopharmaceutical company focused on developing novel oncology product candidates to improve the lives of patients with cancer where treatment options are limited. NewLink Genetics' IDO pathway inhibitors, indoximod and its prodrug, NLG802, are immunology drug candidates designed to harness multiple components of the immune system to combat cancer. For more information, please visit [www.NewLinkGenetics.com](http://www.NewLinkGenetics.com).

#### **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 "forecast," "projected," "guidance," "upcoming," "will," "plan," "intend," "anticipate," "approximate," "expect," "potential," 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, impact of management changes, organizational restructuring, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; statements about NewLink Genetics' expectations regarding the capitalization, resources and ownership structure of the combined company; NewLink Genetics' expectations regarding the sufficiency of the combined company's resources to fund the advancement of any development program or the completion of any clinical trial; statements about the potential benefits of the transaction; the expected completion and timing of the transaction and other information relating to the transaction; expected costs associated with termination benefits and financial impact of the reduction in force, 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 Genetics makes due to a number of important factors, including (i) the risk that the transaction may not be completed in a timely manner or at all, which may adversely affect the NewLink Genetics' business and the price of the common stock of NewLink Genetics, (ii) the failure to satisfy of the conditions to the consummation of the transaction, including approval of the issuance of shares of NewLink Genetics common stock in the transaction or the contemplated reverse stock split, (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, (iv) the risk that the definitive merger agreement may be terminated in circumstances that require NewLink Genetics to pay a termination fee to Lumos Pharma; (v) risks related to the ability to realize the anticipated benefits of the transaction, including the risk that the businesses will not be integrated successfully, (vi) the effect of the announcement or pendency of the transaction on NewLink Genetics' business relationships, operating results and business generally, (vii) risks that the proposed transaction disrupts current plans and operations, (viii) risks related to diverting management's attention from NewLink Genetics' ongoing business operations, (ix) other business effects, including the effects of industry, market, economic, political or regulatory conditions, future exchange and interest rates, and changes in tax and other laws, regulations, rates and policies, (x) the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data, (xi) the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; (xii) risks related to cost reduction efforts; (xiii) NewLink Genetics' workforce reduction costs may be greater than anticipated and the workforce reduction may have an adverse impact on the NewLink Genetics' development activities; and (xiv) the outcome of any legal proceedings that may be instituted against NewLink Genetics related to the merger agreement or the transaction. Further risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements are discussed in "Risk Factors" and elsewhere in NewLink Genetics' Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 and other reports filed with the SEC. The forward-looking statements in this press release represent NewLink Genetics' views as of the date of this press release. NewLink Genetics 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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