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FDA Gives NewLink Genetics Approval to Proceed to Phase 1 Clinical Studies of Their Ebola Vaccine

AMES, IA -- (Marketwired) -- 09/04/14 -- NewLink Genetics Corporation (NASDAQ: NLNK) today announced that the United States Food and Drug Administration (FDA) has given permission for the Company to proceed to Phase 1 clinical trials with their Ebola vaccine candidate. This vaccine was initially developed by the Public Health Agency of Canada (PHAC), and is under an exclusive licensing arrangement with BioProtection Systems, a wholly-owned subsidiary of NewLink Genetics. This vaccine has shown promise in both pre- and post-exposure vaccination of non-human primates exposed to lethal doses of the Ebola virus, and FDA permission allows NewLink to proceed to human clinical trials. NewLink Genetics is working with the U.S. Department of Defense's Defense Threat Reduction Agency (DTRA) and the Walter Reed Army Institute of Research (WRAIR) to launch the initial Phase 1 safety trial.

Current public health measures have not been fully effective and there is general agreement that an effective vaccine against Ebola Virus Disease (EVD) could play a vital role in breaking the chain of transmission. The vaccine to be used by NewLink Genetics was developed originally in Canada and has been studied extensively in non-human primates with very encouraging results. The Phase 1 study planned by the company in collaboration with WRAIR and DTRA will evaluate how healthy adults respond to various doses of vaccine. At the highest doses planned for the trial, the vaccine has worked rapidly enough to be effective in non-human primates even when given after animals were challenged with lethal doses of Ebola virus.

The vaccine is directed at the protein which forms the outer coat of Ebola virus and has been shown to induce antibodies that neutralize the virus. Roughly 40 healthy volunteers will be immunized and then followed to determine the safety of the vaccine and the magnitude and durability of any immune response, including whether these volunteers develop the same levels of antibody responses that are thought to protect monkeys in Ebola challenge studies.

NewLink anticipates additional Phase 1 studies will be undertaken to examine different dosing schedules and extension to vulnerable populations. These studies are planned to be conducted with other collaborators such as National Institute of Allergy and Infectious Disease (NIAID), PHAC, and the World Health Organization (WHO). The need to gather this information is driven by the ongoing spread of EVD in West Africa, where at least six countries have now reported cases of the deadly disease. NewLink has formed a steering committee among its partners to identify and create the necessary scientific, regulatory and ethical framework to expeditiously proceed in the development of this promising vaccine candidate.

"We are pleased to have received FDA permission to proceed with human clinical trials after a rigorous, expedited review. Our goal is to empower our research partners to conduct scientifically sound and ethically appropriate first in human studies. We believe that the quality and due care used in the design and execution of these early studies will be a critical factor in moving this vaccine forward. We are preparing for Phase 1 studies in North America, Europe and Africa, and recently signed agreements with third-party manufacturers to scale up vaccine production," said Dr. Charles Link, CEO and Chief Scientific Officer of NewLink Genetics. "NewLink's team will be in Geneva this week at the WHO Ebola meeting to continue the process of sharing information and planning for additional studies," he added.

"The cooperation of multiple agencies including the PHAC, and US agencies such as the FDA, DTRA and NIAID, has made it possible to very rapidly bring this product to clinical trials at Walter Reed. This support has significantly accelerated the timeline for advancement of this promising vaccine candidate. With the addition of WHO partners, we look forward to expanding the scope of early stage trials," said Dr. Nick Vahanian, President and Chief Medical Officer of NewLink Genetics.

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information please visit <http://www.linkp.com>.

About BioProtection Systems Corporation

BioProtection Systems (BPS), a wholly-owned subsidiary of NewLink Genetics Corporation, is focused on the research, development and commercialization of vaccines. BPS is focused on control of emerging infectious diseases, including improvement of existing vaccines and providing rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism. BPS is based on three core technologies that can be leveraged into the infectious disease or biodefense fields. The first technology is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses. The second is our HyperAcute® immunotherapy technology, which is currently focused on enhancing vaccines for influenza but can be adapted to a number of vaccines. The third technology is based on the yellow fever virus vaccine strain.

About rVSV Vaccine Platform

This vaccine platform is based on attenuated strains of vesicular stomatitis virus, a common animal virus, modified to express an Ebola virus protein that is non-pathogenic in primates and mice. This vaccine was initially developed by the Public Health Agency of Canada (PHAC) with a significant portion of the funding coming from the CBRN Research and Technology Initiative, a federal program led by Defence Research and Development Canada, the research arm of Canada's Department of National Defence, which funded work at the PHAC's National Microbiological Laboratory resulting in the creation of the experimental vaccine, rVSV-ZEBOV-GP (BPSC1001). In 2010, PHAC signed a licensing arrangement with BioProtection Systems (BPS), a wholly-owned subsidiary of NewLink Genetics, as the sole licensee for these vaccines and the underlying technology. BPS has worked with PHAC to produce clinical trial materials and to move this vaccine candidate into Phase 1 studies.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," 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 regarding the following: plans with regard to our infectious disease division; the potential for development of an Ebola vaccine; the prospects and efficacy of our Ebola vaccine candidate; plans to develop and commercialize our product candidates; the timing and outcomes of planned clinical studies; 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's Annual Report on Form 10-K for the period ended December 31, 2013, Quarterly Report on Form 10-Q for the period ended June 30, 2014, Form S-3 Registration Statement filed December 28, 2012 and in its other filings with the Securities and Exchange Commission. 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's views as of any date subsequent to the date of this press release.

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