



July 3, 2014

## **Tekmira Receives Notice of Clinical Hold for TKM-Ebola Phase I Clinical Trial**

VANCOUVER, British Columbia, July 3, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced that the Company has received verbal notice from the U. S. Food and Drug Administration (FDA) that the TKM-Ebola Phase I healthy volunteer clinical study has been placed on clinical hold. This notice applies only to this study.

"We have completed the single ascending dose portion of this study in healthy volunteers without the use of steroid pre-medication. The FDA has requested additional data related to the mechanism of cytokine release, observed at higher doses, which we believe is well understood, and a protocol modification designed to ensure the safety of healthy volunteer subjects, before we proceed with the multiple ascending dose portion of our TKM-Ebola Phase I trial," said Dr. Mark Murray, President and CEO of Tekmira Pharmaceuticals. "We will continue our dialogue with the FDA, provided for under our Fast Track status, in order to advance the development of this important therapeutic agent."

### **About the TKM- Ebola Phase I Clinical Trial**

The TKM-Ebola Phase I clinical trial is a randomized, single-blind, placebo-controlled study and involves single ascending doses and multiple ascending doses of TKM-Ebola. The study is assessing the safety, tolerability and pharmacokinetics of administering TKM-Ebola to healthy adult volunteers without administering any steroid pre-medications.

### **About TKM-Ebola, an Anti-Ebola Virus RNAi Therapeutic**

TKM-Ebola, an anti-Ebola virus RNAi therapeutic, is being developed under a \$140 million contract with the U.S. Department of Defense's Medical Countermeasure Systems BioDefense Therapeutics (MCS-BDTX) Joint Product Management Office. Earlier preclinical studies were published in the medical journal *The Lancet* and demonstrated that when siRNA targeting the Ebola virus and delivered by Tekmira's LNP technology were used to treat previously infected non-human primates, the result was 100 percent protection from an otherwise lethal dose of Zaire Ebola virus (Geisbert et al., *The Lancet*, Vol 375, May 29, 2010). In March 2014, Tekmira was granted a Fast Track designation from the U.S. Food and Drug Administration for the development of TKM-Ebola.

### **About Joint Project Manager Medical Countermeasure Systems (JPM-MCS)**

This work is being conducted under contract with the U.S. Department of Defense Joint Project Manager Medical Countermeasure Systems (JPM-MCS). JPM-MCS, a component of the Joint Program Executive Office for Chemical and Biological Defense, aims to provide U.S. military forces and the nation with safe, effective, and innovative medical solutions to counter chemical, biological, radiological, and nuclear threats. JPM-MCS facilitates the advanced development and acquisition of medical countermeasures and systems to enhance our nation's biodefense response capability. For more information, visit [www.jpeocbd.osd.mil](http://www.jpeocbd.osd.mil).

### **About Tekmira**

Tekmira Pharmaceuticals Corporation is a biopharmaceutical company focused on advancing novel RNAi therapeutics and providing its leading lipid nanoparticle delivery technology to pharmaceutical partners. Tekmira has been working in the field of nucleic acid delivery for over a decade and has broad intellectual property covering LNPs. Further information about Tekmira can be found at [www.tekmira.com](http://www.tekmira.com). Tekmira is based in Vancouver, B.C. Canada.

### **Forward Looking Statements and Information**

This news release contains "forward-looking statements" or "forward-looking information" within the meaning of applicable securities laws (collectively, "forward-looking statements"). Forward-looking statements in this news release include statements about Tekmira's strategy, future operations, clinical trials, prospects and the plans of management; the verbal notice from the FDA that a clinical hold has been placed on the TKM-Ebola Phase I Clinical Trial; and RNAi (ribonucleic acid interference) product development programs.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things, the resumption and completion of the TKM-Ebola Phase I trial. While Tekmira considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause Tekmira's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: Tekmira may not be able to provide additional data and protocol modifications to the FDA for the TKM-Ebola Phase I trial in a timely manner, or at all; the TKM-Ebola Phase I trial may not resume or complete as currently anticipated, or at all; Tekmira's products may not prove to be effective or as potent as currently believed; the FDA may refuse to approve Tekmira's products, or place restrictions on Tekmira's ability to commercialize its products; anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; Tekmira may not receive the necessary regulatory approvals for the clinical development of Tekmira's products; and anticipated payments under contracts with Tekmira's collaborative partners may not be received by Tekmira on a timely basis, or at all, or in the quantum expected by Tekmira.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Report on Form 10-K and Tekmira's continuous disclosure filings, which are available at [www.sedar.com](http://www.sedar.com) or at [www.sec.gov](http://www.sec.gov). All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Tekmira disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

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