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Tekmira Announces Initiation of TKM-Ebola Phase 1 Clinical Trial

Ongoing Collaboration With US Government Advances LNP Technology

VANCOUVER, British Columbia, Feb. 8, 2012 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced the commencement of patient enrollment in its Phase 1 clinical trial for TKM-Ebola.

"The initiation of TKM-Ebola clinical development marks another important milestone for Tekmira. TKM-Ebola continues to be developed under a \$140 million contract with the U.S. Government's Transformational Medical Technologies (TMT) Program, which allows us to advance this program to FDA approval as well as develop further innovations to Tekmira's broader LNP technology platform," said Dr. Mark J. Murray, Tekmira's President and CEO.

The Phase 1 TKM-Ebola clinical trial is a placebo-controlled, single-blind, single-ascending dose study with additional multipleascending dose cohorts in healthy human volunteers. The objective of the Phase 1 trial is to assess the safety and tolerability of TKM-Ebola and evaluate the pharmacokinetics and systemic exposure following both a single-ascending dose (SAD) and multiple-ascending doses (MAD) of TKM-Ebola. A maximum of 56 healthy adult subjects will participate in this study, in two stages. In stage one, the SAD phase will have up to six cohorts with four subjects (three receiving TKM-Ebola and one receiving placebo) in each cohort. In stage two, the MAD portion of the study will have up to three cohorts with four subjects per cohort (three receiving TKM-Ebola and one receiving placebo) in each cohort.

TKM-Ebola will be developed under specific FDA regulatory guidelines (called the "Animal Rule"), which are designed to advance therapeutics that cannot meet the requirements for traditional approval because human efficacy studies are not feasible.

In addition to the TKM-Ebola product development collaboration, the TMT program has supported further development of Tekmira's LNP technology, resulting in a successful 100-fold scale up of the LNP manufacturing process as well as the development of a lyophilization (freeze drying) process while maintaining key LNP product characteristics. These advances will support the late stage clinical development and commercialization of TKM-Ebola as well as other LNP-enabled products.

Tekmira believes its LNP technology represents the most widely adopted delivery technology for the systemic delivery of RNAi therapeutics. Tekmira's LNP platform is being utilized in multiple clinical trials by both Tekmira and its partners.

About TKM-Ebola

Tekmira is developing TKM-Ebola, a systemically delivered RNAi therapeutic that utilizes Tekmira's lipid nanoparticle (LNP) delivery technology, for the treatment of Ebola virus infection. There are no approved treatments for Ebola or other hemorrhagic fever viruses. Preclinical studies published in the medical journal *The Lancet* demonstrated that when small interfering RNA (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).

About RNAi and Tekmira's LNP Technology

RNAi therapeutics have the potential to treat a broad number of human diseases by "silencing" disease causing genes. The discoverers of RNAi, a gene silencing mechanism used by all cells, were awarded the 2006 Nobel Prize for Physiology or Medicine. RNAi therapeutics, such as "siRNAs," require delivery technology to be effective systemically. Tekmira believes its LNP technology represents the most widely adopted delivery technology for the systemic delivery of RNAi therapeutics. Tekmira's LNP platform is being utilized in multiple clinical trials by both Tekmira and its partners. Tekmira's LNP technology (formerly referred to as stable nucleic acid-lipid particles or SNALP) encapsulates siRNAs with high efficiency in uniform lipid nanoparticles that are effective in delivering RNAi therapeutics to disease sites in numerous preclinical models. Tekmira's LNP formulations are manufactured by a proprietary method which is robust, scalable and highly reproducible and LNP-based products have been reviewed by multiple FDA divisions for use in clinical trials. LNP formulations comprise several lipid components that can be adjusted to suit the specific application.

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 <u>www.tekmirapharm.com</u>. Tekmira is based in Vancouver, B.C.

The Tekmira Pharmaceuticals logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=8319

About the Joint Project Manager Transformational Medical Technologies (TMT) Program

The Joint Project Manager Transformational Medical Technologies (JPM-TMT) Program supports the overall mission of the U.S. Department of Defense (DoD) by protecting the Warfighter and the nation from emerging, genetically engineered or unknown biothreats. Chartered within the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), JPM-TMT partners with the DoD, other government agencies, academia, and industry for the advanced development of adaptable platform technologies that can be rapidly tailored and deployed to mitigate the effects of the unknown threat, whether it be naturally occurring or man-made. Program investments target the most difficult challenges of medical capability development and fill gaps not currently addressed by the biodefense community. For more information, visit www.jpmtmt.mil.

Forward-Looking Statements and Information

This press release contains "forward-looking statements" or "forward-looking information" within the meaning of applicable securities laws (collectively, "forward-looking statements"). Forward-looking statements are generally identifiable by use of the words "believes," "may," "plans," "will," "anticipates," "intends," "budgets," "could," "estimates," "expects," "forecasts," "projects" and similar expressions, and the negative of such expressions. Forward-looking statements in this news release include statements about Tekmira's strategy, future operations, clinical trials, prospects and plans of management; Tekmira's RNAi product development programs; the effects of TKM-Ebola as a treatment of the Ebola virus; the timing of the Phase 1 clinical trial for TKM-Ebola; the advancement of the TKM-Ebola program to FDA approval; further innovations to Tekmira's LNP technology platform; further development of Tekmira's technology that support late stage clinical development and commercialization of TKM-Ebola as well as other LNP-enabled products; and the timing of approval of TKM-Ebola.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things: LNP's status as a leading RNAi delivery technology; the effectiveness of Tekmira's TKM-Ebola product candidate as a treatment for the Ebola virus; the timing of the clinical trial for TKM-Ebola; and the timing of approval of TKM-Ebola. 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: the possibility that a Phase 1 clinical trial for TKM-Ebola may not be initiated in the anticipated timeframe or at all; TKM-Ebola may never receive FDA approval; there may be no further innovations to Tekmira's LNP technology platform; further development of Tekmira's LNP technology may not support late stage clinical development and commercialization of TKM-Ebola or other LNP-enabled products; the possibility that other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; and Tekmira's development programs, including TKM-Ebola, will not result in expected results on a timely basis, or at all.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Information Form dated March 30, 2011 and available at <u>www.sedar.com</u> or at <u>www.sec.gov/edgar</u>. 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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