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Tekmira Pharmaceuticals Receives Approval from FDA to Initiate TKM-Ebola Phase 1 Clinical Trial

VANCOUVER, British Columbia, Nov. 28, 2011 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX: TKM), a leading developer of RNA interference (RNAi) therapeutics, announced today that its Investigational New Drug (IND) application for TKM-Ebola has been approved by the United States Food and Drug Administration (FDA) allowing Tekmira to initiate a Phase 1 clinical trial.

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).

"We are pleased to have received the FDA's approval of our TKM-Ebola IND. With this approval, we remain on track to achieve another significant milestone for the company by initiating the Phase 1 clinical trial of this product in early 2012," said Dr. Mark J. Murray, Tekmira's President and CEO.

"TKM-Ebola is being developed under a \$140 million contract awarded to us by the U.S. Government's Transformational Medical Technologies (TMT) Program. We look forward to continuing this successful collaboration to drive the TKM-Ebola program forward in clinical development," added Dr. Murray.

In addition to the TKM-Ebola product development work sponsored by TMT, this 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 lyophilization (freeze drying) processes while maintaining key LNP product characteristics. These advances will support the late stage clinical development and commercialization of TKM-Ebola and Tekmira's other LNP 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 the Phase 1 TKM-Ebola Clinical Trial

The Phase 1 TKM-Ebola clinical trial is a placebo-controlled, single-blind, single-ascending dose study with additional multiple-ascending 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 and multiple-ascending doses of TKM-Ebola. 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.

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 www.tekmirapharm.com. 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; and the timing of the initiation of a Phase 1 clinical trial for 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; and the timing of initiation of a clinical trial for 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; 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 www.sedar.com or at www.sec.gov/edgar. 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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