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Tekmira Receives Fast Track Designation From FDA for Its Anti-Ebola Viral Therapeutic

VANCOUVER, British Columbia, March 5, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of TKM-Ebola, an anti-Ebola viral therapeutic.

The FDA's Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions.[1]

"This is an important milestone for Tekmira and our TKM-Ebola program. Receiving a Fast Track designation from the FDA supports our work to advance the development of this therapeutic as quickly as possible. Our leadership in developing anti-viral therapies has been supported by our collaboration with the U.S. Department of Defense, which is funding the development of TKM-Ebola," said Dr. Mark J. Murray, Tekmira's President and CEO.

"In January, we announced that the first subject had been dosed in a Phase I clinical trial evaluating the safety of our TKM-Ebola therapeutic, which utilizes a third-generation LNP formulation. We continue to enroll subjects and remain on track to have data from this trial available in the second half of this year," added Dr. Murray.

Tekmira's anti-viral product platform includes RNAi therapeutics addressing chronic Hepatitis B infection and lethal hemorrhagic fever viruses, including Ebola and Marburg.

About the TKM-Ebola Phase I Clinical Trial

The TKM-Ebola Phase I clinical trial is a randomized, single-blind, placebo-controlled study involving 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 subjects. Four subjects are planned per cohort. There are four planned cohorts for a total of 16 subjects in the single dose arm, and three planned cohorts for a total of 12 subjects in the multiple dose arm of the trial. Each cohort will enroll three subjects who receive TKM-Ebola, and one who will receive a placebo.

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). Tekmira's productive collaboration with the MCS-BDTX was modified and expanded in 2013 to include significant advances in LNP formulation technology since the initiation of the program in 2010.

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.

About RNAi and Tekmira's LNP

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.

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 the FDA's Fast Track designation of TKM-Ebola; Phase I human clinical trial of TKM-Ebola and the contract with the U.S. Department of Defense; timing and availability of data from the Phase I human clinical trial; future RNAi-based anti-viral therapeutics; and Tekmira's strategy, future operations, prospects and the plans of management.

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; and the timing and quantum of payments to be received under contracts with Tekmira's partners. 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: TKM-Ebola may not prove to be an effective anti-viral therapy for hemorrhagic fever viruses; data from the TKM-Ebola Phase I human clinical trial may not be available as currently anticipated, or at all; the U.S. Department of Defense may suspend or terminate its participation in the TKM-Ebola program; the Fast Track designation from the FDA may not result in faster development times or earlier approvals; and Tekmira's products may not prove to be effective or as potent as currently believed.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Report on Form 20-F for the year ended December 31, 2012, which is 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.

[1] Taken from FDA website at:
http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccesstoImportantNewTherapies/ucm128291.htm

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