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Tekmira Establishes Manufacturing and Clinical Trial Agreement to Provide TKM-Ebola-Guinea for Clinical Studies in West Africa

VANCOUVER, British Columbia, Dec. 22, 2014 (GLOBE NEWSWIRE) -- Tekmira Pharmaceuticals Corporation (Nasdaq:TKMR) (TSX:TKM), a leading developer of RNA interference (RNAi) therapeutics, announced today that the Company has entered into a Manufacturing and Clinical Trial Agreement with the University of Oxford to provide the new TKM-Ebola-Guinea therapeutic product for clinical studies in West Africa. The studies are expected to commence early next year, subject to finalization of a suitable clinical protocol.

The University of Oxford is the representative of the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC). ISARIC will conduct clinical studies of TKM-Ebola-Guinea in Ebola virus infected patients, with funding provided by the Wellcome Trust. GMP manufacture of TKM-Ebola-Guinea is now complete and 100 treatment courses are available for the study.

"We are very pleased that TKM-Ebola-Guinea will be studied in patients and result in benefit to them. While the clinical protocol is still being finalized, the studies are designed to establish efficacy, so that an effective therapeutic can be available to patients," said Dr. Mark J. Murray, Tekmira's President and CEO.

In early October, the genomic sequence of the Ebola-Guinea variant, which is responsible for the current outbreak in West Africa, was determined from several viral isolates and was published in the *New England Journal of Medicine*¹. Tekmira developed a modified RNAi therapeutic to specifically target the Ebola-Guinea variant. The new product, TKM-Ebola-Guinea, is designed to match the genomic sequence exactly, with two RNAi triggers.

Results of preclinical studies with TKM-Ebola-Guinea demonstrated efficacy results comparable to those obtained with TKM-Ebola, which has demonstrated up to 100% protection from an otherwise lethal dose of the virus.

"TKM-Ebola-Guinea underscores how RNAi-based technology allows for rapid response to emerging viral variants," said Dr. Murray.

About TKM-Ebola-Guinea, an Anti-Ebola RNAi Therapeutic Targeting Ebola-Guinea

The Ebola-Guinea strain is the virus responsible for the current outbreak in West Africa. This strain diverges slightly from the Kikwit strain, which was the original target of TKM-Ebola. The genomic sequence of the Ebola-Guinea strain was determined from several viral isolates and published in the *New England Journal of Medicine* in October 2014¹. Tekmira developed a modified RNAi therapeutic, based on the Company's original TKM-Ebola investigational therapeutic, to specifically target Ebola-Guinea. The new product, termed TKM-Ebola-Guinea, is designed to match the genomic sequence exactly, with two RNAi triggers. The ability to rapidly and accurately match the evolving genetic sequences of emerging infectious agents is one of the powerful features of RNAi therapeutics.

About TKM-Ebola, an Anti-Ebola 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 (JPM-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 RNAi and Tekmira's LNP

RNAi therapeutics have the potential to treat a 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 trigger molecules often require delivery technology to be effective as therapeutics. Tekmira believes its LNP

technology represents the most advanced and widely adopted delivery technology for the systemic delivery of RNAi triggers. Tekmira's LNP platform is being utilized in multiple clinical trials in various disease areas by Tekmira and its partners. Tekmira's LNP technology (formerly referred to as stable nucleic acid-lipid particles or SNALP) encapsulates RNAi triggers with high efficiency in uniform lipid nanoparticles that are effective in delivering these therapeutic compounds to disease sites. 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 regulatory agencies for use in clinical trials. LNP formulations comprise several lipid components that can be adjusted to suit the specific application.

About Joint Project Manager Medical Countermeasure Systems BioDefense Therapeutics (JPM-MCS-BDTX)

Tekmira's Ebola program is being conducted under a \$140M contract with the U.S. Department of Defense (DoD) Joint Project Manager Medical Countermeasure Systems BioDefense Therapeutics (JPM-MCS-BDTX). JPM-MCS-BDTX, 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 biodefense response capability. For more information, visit www.jpeocbd.osd.mil.

About Wellcome Trust

The Wellcome Trust is a global charitable foundation dedicated to improving health. We provide more than £700 million a year to support bright minds in science, the humanities and the social sciences, as well as education, public engagement and the application of research to medicine. Our investment portfolio gives us the independence to support such transformative work as the sequencing and understanding of the human genome, research that established front-line drugs for malaria, and Wellcome Collection, our free venue for the incurably curious that explores medicine, life and art. www.wellcome.ac.uk.

Oxford University's Medical Sciences Division

Oxford University's Medical Sciences Division is one of the largest biomedical research centres in Europe, with over 2,500 people involved in research and more than 2,800 students. The University is rated the best in the world for medicine, and it is home to the UK's top-ranked medical school. From the genetic and molecular basis of disease to the latest advances in neuroscience, Oxford is at the forefront of medical research. It has one of the largest clinical trial portfolios in the UK and great expertise in taking discoveries from the lab into the clinic. Partnerships with the local NHS Trusts enable patients to benefit from close links between medical research and healthcare delivery. A great strength of Oxford medicine is its long-standing network of clinical research units in Asia and Africa, enabling world-leading research on the most pressing global health challenges such as malaria, TB, HIV/AIDS and flu. Oxford is also renowned for its large-scale studies which examine the role of factors such as smoking, alcohol and diet on cancer, heart disease and other conditions.

About Tekmira

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

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 manufacturing and clinical trial agreement with the University of Oxford to provide TKM-Ebola-Guinea product for clinical trials in West Africa; the commencement of a study and finalization of acceptable protocol; Tekmira's collaboration with an international consortium to provide an RNAi based investigational therapeutic for expedited clinical trials of Ebola virus therapeutics in West Africa; the funding of the consortium from the Wellcome Trust; and the creation of appropriate clinical and regulatory frameworks for the potential use of investigational therapeutics in Africa.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things, the effectiveness of RNAi therapeutics in the treatment of Ebola virus and the adequacy of funding from the Wellcome Trust for the anticipated program of the international consortium. 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: RNAi based therapeutics may not prove to be effective in the treatment of Ebola virus as currently anticipated, compared to other therapeutics, or at all; funding provided by the Wellcome Trust may not be adequate for the anticipated program of the international consortium; manufacture of investigational therapeutics or the establishment of operational clinical trial platforms may not occur as currently anticipated, or at all; there can be no assurances that Tekmira's product will be selected by the consortium or be given to patients for treatment; Tekmira may not produce an RNAi based product targeting the viral variant responsible for the current outbreak in West Africa as currently anticipated, or at all; appropriate clinical and regulatory frameworks for the potential use of investigational therapeutics in Africa may never be established, or may not be beneficial to Tekmira's products; 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; and Tekmira may not receive the necessary regulatory approvals for the clinical development of Tekmira's products.

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 or 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.

Reference

¹ Baize S., Pannetier D., Oestereich L., et al. "Emergence of Zaire Ebola Virus Disease in Guinea." **New England Journal of Medicine**. October 9, 2014 Vol. 371 No. 15

CONTACT: Investors

Julie P. Rezler

Director, Investor Relations

Phone: 604-419-3200

Email: jrezler@tekmira.com

Media

Please direct all media inquiries to media@tekmira.com