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# Tekmira Pharmaceuticals Files IND Application with U.S. FDA for PLK1 SNALP

## Clinical Trial for RNAi Cancer Program on Track to Commence in Second Half of 2010

**VANCOUVER, BC** — Tekmira Pharmaceuticals Corporation (TSX: TKM), a leader in RNA interference (RNAi) therapeutics, today announced it has filed an Investigational New Drug (IND) application seeking approval from the United States Food and Drug Administration (FDA) to begin a Phase 1 human clinical trial to evaluate PLK1 SNALP as a treatment for solid tumor cancers.

Dr. Mark J. Murray, Tekmira's President and CEO, said, "With the filing of our PLK1 SNALP IND, we are on track to begin a Phase 1 human clinical trial with our second RNAi clinical product candidate in the second half of this year. This is another important milestone for Tekmira as we continue to both advance our own pipeline of RNAi drug candidates and support our partners as they move forward with their own RNAi programs using our leading SNALP delivery technology."

The FDA has 30 days to review Tekmira's IND application for PLK1 SNALP and to request any additional information before permitting the clinical trial to proceed. At the end of the FDA review period, Tekmira will provide additional details of the PLK1 SNALP Phase 1 human clinical trial, which is expected to begin in the second half of 2010.

Tekmira's therapeutic approach to treating cancer is to target PLK1 (polo-like kinase 1), a protein involved in tumor cell proliferation and a validated oncology target. In preclinical studies, PLK1 SNALP displayed potent and specific anti-tumor effects in a variety of tumor models in animals including preclinical models of tumors outside the liver. Tekmira's work on PLK1 SNALP was published in the Journal of Clinical Investigation (Judge et al, Confirming the RNAi-mediated mechanism of action of siRNA-based cancer therapeutics. JCI. 23 Feb 09).

### About RNAi and SNALP

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. Lipid nanoparticles (LNPs) are one of the most widely used siRNA delivery approaches for systemic administration. Tekmira's SNALP (stable nucleic acid-lipid particles) technology is the leading class of LNPs being used in clinical development. SNALP technology encapsulates siRNAs with high efficiency in uniform lipid nanoparticles which are effective in delivering RNAi therapeutics to disease sites in numerous preclinical models. SNALP formulations are manufactured by a proprietary method which is robust, scalable and highly reproducible. SNALP-based products have been reviewed by multiple FDA divisions for use in clinical trials. SNALP 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 SNALP and LNPs. Further information about Tekmira can be found at <u>www.tekmirapharm.com</u>. Tekmira is based in Vancouver, B.C.

### 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 PLK1 SNALP as a treatment of cancer; and the timing of the initiation of a clinical trial for PLK1 SNALP.

With respect to the forward-looking statements contained in this news release, Tekmira has made numerous assumptions regarding, among other things: SNALP's status as a leading RNAi delivery technology; the effectiveness of Tekmira's PLK1 SNALP product candidate as a treatment for cancer; and FDA approval with respect to commencing a clinical trial for PLK1 SNALP. 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 other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; the FDA will not approve to the commencement of Tekmira's planned clinical trials, including PLK1 SNALP; and Tekmira's development programs 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 31, 2010 available at <u>www.sedar.com</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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