

May 7, 2009

# Tekmira Pharmaceuticals Receives Clearance from FDA to Initiate ApoB SNALP Phase 1 Clinical Trial

**Vancouver, BC** — Tekmira Pharmaceuticals Corporation (TSX: TKM) announced today that its Investigational New Drug (IND) application for ApoB SNALP has been cleared by the United States Food and Drug Administration (FDA) allowing Tekmira to begin enrolling patients in a Phase 1 human clinical trial. ApoB SNALP, Tekmira's lead RNAi therapeutic product candidate, is being developed as a treatment for patients with elevated low-density lipoprotein (LDL) cholesterol, or "bad" cholesterol. ApoB SNALP is designed to reduce the production of apolipoprotein B (ApoB), a protein produced in the liver that plays a central role in cholesterol metabolism.

Dr. Mark J. Murray, Tekmira's President and CEO, said "The successful FDA review of our ApoB SNALP IND is a testament to the scientific quality of our IND submission. We remain on track to achieve our milestone of initiating a Phase 1 clinical trial before mid-year in patients with high cholesterol."

The Phase 1 clinical trial will evaluate the safety, tolerability and pharmacokinetics of escalating single doses of ApoB SNALP in approximately 30 patients with elevated LDL cholesterol. The trial is also designed to provide preliminary data on the ability of ApoB SNALP to lower serum LDL cholesterol levels. Phase 1 data is expected to be available late 2009 or early 2010.

Tekmira's therapeutic approach is to target ApoB, a protein synthesized in the liver that is essential to the assembly and secretion of very low density lipoprotein (VLDL), a precursor to LDL, both of which are required for the transport and metabolism of cholesterol. ApoB SNALP consists of small interfering RNA (siRNA), designed to silence ApoB, encapsulated in a SNALP formulation. ApoB SNALP is delivered with high efficiency into the liver hepatocytes, the cells which produce ApoB, where the siRNA acts to silence the mRNA coding for ApoB protein resulting in a decrease in circulating VLDL and LDL.

The therapeutic activity of ApoB SNALP has been demonstrated in preclinical models of high cholesterol. Rodents fed a high fat diet demonstrate a 50-100% increase in total cholesterol in the blood. A single ApoB SNALP treatment can overcome such diet-induced high cholesterol, returning blood cholesterol levels to normal. The suppressive effects of a single ApoB SNALP dose lasts for several weeks in preclinical models of high cholesterol.

### About RNAi and SNALP

RNAi drugs have the potential to treat human diseases by "switching-off" disease causing genes. The technology, representing one of the most promising and rapidly advancing frontiers in biology and drug discovery, was awarded the 2006 Nobel Prize for Physiology or Medicine. RNAi drugs, such as siRNA, require delivery technology to be administered systemically. In preclinical studies, Tekmira's SNALP (stable nucleic acid-lipid particles) technology has been shown to be a safe and effective way to deliver RNAi drugs to disease sites. Tekmira believes it has a leading intellectual property position in the field of siRNA delivery.

### 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. 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**

There are forward-looking statements and information contained herein that are not based on historical fact, including, without limitation, statements containing the words "believes," "may," "plans," "will," "estimate," "continue," "anticipates," "intends," "expects," and similar expressions, and the negative of such expressions. These statements are only predictions.

Forward-looking statements and information should be considered carefully. Undue reliance should not be placed on forward-looking statements and information as there can be no assurance that the plans, intentions or expectations upon which they are based will occur. By their nature, forward-looking statements and information involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, which contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements and information will not occur and may cause actual results or events to differ materially from those anticipated in such forward-looking statements and information.

With respect to the timing of the clinical trial discussed in this news release, there are circumstances that may cause the

commencement and completion of the trial to be different than the time periods currently anticipated. These factors include delays in initiating and completing patient enrolment and the occurrence of adverse events. In addition, clinical trials may not demonstrate safety and efficacy in humans or the drug candidates may fail in development or be delayed to a point where they do not become commercially viable. With respect to the pre-clinical results discussed in this news release, there is no certainty that human clinical results will be consistent with pre-clinical results.

The business of Tekmira is also subject to other risks and factors that may cause actual results, events or developments to be materially different from any future results, events or developments expressed or implied by any forward-looking statement and information. Such factors include, among others, the stage of development of Tekmira, lack of product revenues, additional capital requirements, the need to obtain regulatory approval to commence clinical trials, risks associated with the completion of clinical trials and obtaining regulatory approval to market Tekmira's products, the safety and efficacy of Tekmira's products, the ability to protect Tekmira's intellectual property and dependence on collaborative partners.

A more complete discussion of the risks and uncertainties facing Tekmira appears in Tekmira's Annual Information Form dated March 31, 2009 available at <u>www.sedar.com</u>. Tekmira disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements or information contained herein to reflect future results, events or developments, except as required by law.

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