

July 7, 2010

# Tekmira's Partner Alnylam Initiates Dosing in a Phase 1 Clinical Trial of ALN-TTR01

## -ALN-TTR01 Utilizes Tekmira's Leading SNALP Delivery Technology-

**Vancouver, BC** — Tekmira Pharmaceuticals Corporation (TSX: TKM), a leading developer of RNA interference (RNAi) therapeutics, announced today that one of the company's partners, Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY) has initiated dosing in a Phase 1 human clinical trial of its product candidate ALN-TTR01. The study is designed to evaluate the safety and tolerability of ALN-TTR01 in patients with transthyretin (TTR)-mediated amyloidosis (ATTR), a disease that results in damage to the peripheral nerves and heart. The trial is also designed to provide preliminary data on human proof of concept based on measurements of TTR serum levels. ALN-TTR01 is a systemic RNAi therapeutic that uses Tekmira's leading lipid nanoparticle delivery technology, SNALP (stable nucleic acid-lipid particles).

Dr. Mark J. Murray, Tekmira's President and CEO, said, "We are pleased that Alnylam has initiated dosing in a Phase 1 human clinical trial of ALN-TTR01, as this expands the potential for SNALP-enabled RNAi therapeutics. This also represents a SNALP-based product cleared by European regulatory agencies for human clinical testing and triggers a milestone payment to Tekmira. We continue to support Alnylam in the advancement of their systemic product candidates, including ALN-TTR01, and provide drug product through an exclusive manufacturing agreement."

ALN-TTR01 is being developed as a treatment of transthyretin (TTR)-mediated amyloidosis (ATTR). ATTR is caused by mutations in the TTR gene, which is expressed predominantly in the liver, and results in the accumulation of pathogenic deposits of amyloid proteins in multiple tissues, including the peripheral nervous system, heart, and the gastrointestinal tract.

Alnylam's Phase 1 trial will be conducted in Portugal, Sweden, and the U.K., and is a randomized, blinded, placebo-controlled dose escalation study designed to enroll approximately 28 ATTR patients. The primary objective is to evaluate the safety and tolerability of a single dose of intravenous ALN-TTR01 and secondary objectives include characterization of plasma and urine pharmacokinetics of ALN-TTR01 and assessment of pharmacodynamic activity based on measurements of circulating TTR serum levels.

## **About TTR-Mediated Amyloidosis**

TTR-mediated amyloidosis (ATTR) is a hereditary, systemic disease caused by a mutation in the transthyretin (TTR) gene. TTR protein is produced primarily in the liver and is normally a carrier for thyroid hormones and retinol binding proteins. The mutation causes abnormal amyloid proteins to accumulate in and damage body organs and tissue such as the peripheral nerves and heart, resulting in intractable peripheral sensory neuropathy, autonomic neuropathy, and cardiomyopathy. In its severest form, ATTR represents a tremendous unmet medical need with significant morbidity and mortality as an orphan disease; combined, FAP (familial amyloidotic polyneuropathy) and FAC (familial amyloidotic cardiomyopathy) affect approximately 50,000 people worldwide. ATTR patients with FAP have a mean life expectancy of five to 15 years from symptom onset and the only treatment option is liver transplantation; as a result there is a significant need for novel therapeutics to treat patients who have a mutation in the TTR gene.

## 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 "siRNA," 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.

#### Tekmira 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 Alnylam's ALN-TTR01 RNAi product development program including the Phase 1 human clinical trial of ALN-TTR01; the advancement of products that utilize Tekmira's lipid nanoparticle technology; the advancement of ALN-TTR01 through clinical development and commercialization with corresponding milestone and royalty payments to Tekmira; and the use of SNALP technology by Tekmira's licensees.

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 and payments to be received under contracts with Tekmira's collaborative 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: the possibility that other organizations have made advancements in RNAi delivery technology that Tekmira is not aware of; Tekmira's development partners and licensees conducting clinical trials and development programs, including Alnylam's Phase 1 human clinical trial of ALN-TTR01, will not result in expected results on a timely basis, or at all; anticipated payments under contracts with Tekmira's collaborative partners will not be received by Tekmira on a timely basis, or at all, or in the quantum expected by Tekmira; clinical trials may not generate results that warrant future development of the tested drug candidate; funding from research and product development partners may not be provided when required under agreements with those partners.

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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