

October 17, 2011



Acasti Pharma Inc. Receives Health Canada Clearance for an Open-Label Phase II Hypertriglyceridemia Trial

LAVAL, Quebec, Oct. 17, 2011 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (Acasti) (TSX.V:APO), a subsidiary of Neptune Technologies & Bioresources Inc. (Neptune), has received another positive response from Health Canada regarding its second Clinical Trial Application (CTA), thereby allowing the initiation of an open-label phase II clinical trial with CaPre®.

Health Canada informed Acasti that there was no objection to Acasti's proposed study based on the information and material provided to support the CTA. Therefore, Acasti will initiate an open-label phase II human clinical trial to investigate the dose response effect of CaPre® as a treatment for patients with dyslipidemia. Enrollment in the study is expected to commence in the next few weeks with results anticipated early 2012. The design of the study is an open-label trial to assess the safety and efficacy of CaPre® in patients with triglyceride levels ranging from moderately high to very high, which distinguishes CaPre® from prescription drug fish oils labelled only to treat patients with very high levels of triglycerides.

"We are pleased with Health Canada's authorization; it represents another milestone in Acasti's clinical development plan towards positioning CaPre® as a safe and efficacious first-in-class regimen to help manage cardiometabolic disorders" indicated Pierre Lemieux, Ph.D., Chief Operating Officer.

"The ability to initiate this additional Phase II study allows Acasti to generate near-term data to guide our regulatory and clinical strategy. We believe the broad potential activity and safety of CaPre in the wider dyslipidemic population will distinguish our drug from others in this arena. This effort will also help form the basis of our future clinical work in the US and Europe" said Harlan Waksal, M.D., Executive Vice President.

"Acasti has made significant progress over the last few months including this CTA acceptance as well as the recently announced initiation of enrolment in our first Phase II double-blind placebo controlled clinical trial. In addition to our drug development initiatives, the composition of Acasti's active pharmaceutical ingredients is now patented through Acasti's exclusive worldwide license from Neptune Technologies and Bioresources. Neptune was recently granted from the U.S. Patent and Trademark Office ("USPTO") a new patent (U.S. No. 8,030,348) covering omega-3 phospholipids comprising polyunsaturated fatty acids. Furthermore, Acasti recently completed the "Rights Offering" raising over \$8 million dollars" said Tina Sampalis, M.D., Ph.D., President.

[About Acasti Pharma Inc.](#)

Acasti (TSX-V:APO) is developing a product portfolio of proprietary novel long-chain omega-3 phospholipids. Phospholipids are the major component of cell membranes and are essential for all vital cell processes. They are one of the principal constituents of High Density Lipoprotein (good cholesterol) and, as such, play an important role in modulating cholesterol efflux. Acasti Pharma's proprietary novel phospholipids carry and functionalize the polyunsaturated omega-3 fatty acids EPA and DHA, which have been shown to have substantial health benefits and which are stabilized by potent antioxidants. Acasti Pharma is focusing initially on treatments for chronic cardiovascular conditions within the over-the-counter, medical food and prescription drug markets.

About Neptune Technologies & Bioresources Inc.

Neptune (Nasdaq:NEPT) and (TSX-V:NTB) is an industry-recognized leader in the innovation, production and formulation of science-based and clinically proven novel phospholipid products for the nutraceutical and pharmaceutical markets. The Company focuses on growing consumer health markets including cardiovascular, inflammatory and neurological diseases driven by consumers taking a more proactive approach to managing health and preventing disease. The Company sponsors clinical trials aimed to demonstrate its product health benefits and to obtain regulatory approval for label health claims. Neptune is continuously expanding its intellectual property portfolio as well as clinical studies and regulatory approvals. Neptune's products are marketed and distributed in over 20 countries worldwide. Neptune is the mother company of Acasti and NeuroBioPharm.

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Source: Acasti Pharma Inc.