Acasti Pharma Reports Positive CaPre Omega-3 Bridging Study Data

Results Support Streamlined Regulatory Pathway for Novel Hypertriglyceridemia Drug

Laval, Québec, CANADA, Sept. 14, 2016 — Acasti Pharma (NASDAQ:ACST – TSX-V:APO) today announced that its bridging study for novel drug candidate CaPre® (omega-3 phospholipid) has successfully met its objectives, supporting Acasti's strategy to pursue the U.S. Food and Drug Administration's (FDA) 505(b)(2) regulatory pathway for approval. Acasti is developing CaPre for the treatment of patients with severe hypertriglyceridemia, a metabolic condition that contributes to increased risk of cardiovascular disease and pancreatitis. The 505(b)(2) regulatory pathway allows Acasti to streamline the overall development program required to support a New Drug Application (NDA) by relying on the safety data of an approved drug.

"We are confident that the results of this study support the 505(b)(2) regulatory pathway chosen by Acasti to gain marketing approval of CaPre," said Jan D'Alvise, president and CEO of Acasti Pharma. "With this momentum, we look forward to working with the FDA to confirm the pathway and optimize the design of our Phase 3 program, which will seek to demonstrate the safety and efficacy of CaPre in patients with severe hypertriglyceridemia."

Acasti's open-label, randomized, four-way, cross-over, bioavailability study compared CaPre given as a single dose of 4 grams in fasting and fed states with the approved hypertriglyceridemia drug LOVAZA (omega-3-acid ethyl esters) in 56 healthy volunteers. The study met its primary objective and demonstrated that the levels of omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) following administration of CaPre did not exceed the levels following administration of LOVAZA in subjects who were fed a high-fat meal. These results support the basis for claiming a comparable safety profile of the two products.

Furthermore, among subjects in the fasting state, CaPre demonstrated better bioavailability than LOVAZA, as measured by blood levels of EPA and DHA. As previously reported, the bioavailability of CaPre is not significantly reduced when taken with a low-fat meal versus a high-fat meal. This could represent a significant clinical advantage for CaPre since the administration with a low-fat meal represents a more attractive regimen for patients with hypertriglyceridemia who follow a restricted diet.

CaPre is a novel composition of omega-3 phospholipids sourced from krill. Its omega-3s, principally EPA and DHA, are naturally either "free" or bound to phospholipids that help them to be better absorbed into the body. This allows for enhanced bioavailability and EPA and DHA blood levels compared to the "esterified" fish-oil omega-3 options such as LOVAZA. CaPre is designed to modulate the major lipids associated with cardio-metabolic disease: in two previously reported Phase 2 clinical trials, CaPre reduced triglyceride levels, lowered non-high density lipoprotein (non-HDL-C, a useful marker of cardiovascular disease), and increased levels of high density lipoprotein (HDL-C, or "good cholesterol") while having a neutral to positive effect on lowering low density lipoprotein (LDL-C, or "bad cholesterol").

"The CaPre bioavailability study has reinforced the compound's unique attributes in comparison with the leading pharmaceutical agent for hypertriglyceridemia," said Roderick Carter, M.D., chairman of Acasti Pharma. "CaPre demonstrates clinically meaningful effects on many key markers of cardio-

metabolic health. With high rates of obesity and diabetes fueling the number of patients with elevated triglycerides and cholesterols, CaPre could fill the need for a best-in-class omega-3 medication that addresses the full lipid profiles of these patients."

About CaPre

Sourced from krill oil, CaPre seeks to provide a full scope of health benefits to patients with hypertriglyceridemia, filling a medical need that no other omega-3 treatment option has been able to address. CaPre successfully completed Phase 2 clinical trials for the treatment of hypertriglyceridemia, a very common metabolic condition in which blood levels of triglycerides, a type of lipid, are elevated, posing a risk to cardiovascular health. Severe hypertriglyceridemia, affecting more than 4 million adults in the U.S. is associated with an increased risk of coronary artery disease and pancreatitis and is often caused or exacerbated by uncontrolled diabetes mellitus, obesity and sedentary habits. CaPre is intended to be taken orally once per day in capsule form.

About Acasti Pharma

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre, for the treatment of hypertriglyceridemia, a chronic condition affecting an estimated one-third of the U.S. population. Since its founding in 2008, Acasti Pharma has focused on addressing a critical market need for an effective, safe and well-absorbing omega-3 therapeutic that can address patients' complete lipid profile, making a positive impact on all major lipids associated with cardiovascular disease risk. For more information, visit www.acastipharma.com.

Forward Looking Statements

Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. securities laws and Canadian securities laws. Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements labeled with the terms "believes," "belief," "expects," "intends," "anticipates," "will," or "plans" to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

The forward-looking statements contained in this news release are expressly qualified in their entirety by this cautionary statement and the "Cautionary Note Regarding Forward-Looking Information" section contained in Acasti's latest Annual Information Form, which also forms part of Acasti's latest annual report on Form 20-F, and which is available on SEDAR at www.sedar.com, on EDGAR at www.sec.gov/edgar.shtml and on the investor section of Acasti's website at acastipharma.com (the "AIF"). All forward-looking statements in this press release are made as of the date of this press release. Acasti does not undertake to update any such forward-looking statements whether as a result of new information, future events or otherwise, except as required by law. The forward-looking statements contained herein are also subject generally to other risks and uncertainties that are described from time to time in Acasti's public securities filings with the Securities and Exchange Commission and the

Canadian securities commissions. Additional information about these assumptions and risks and uncertainties is contained in the AIF under “Risk Factors.”

Neither NASDAQ, the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

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