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Acasti Pharma Announces First Patient Randomized in Pivotal TRILOGY Phase 3 Program of CaPre in Severe Hypertriglyceridemia

LAVAL, QUÉBEC -- (Marketwired) -- 03/14/18 -- Acasti Pharma Inc. (NASDAQ:ACST)(TSX VENTURE:ACST) today announced that the first patient has been randomized in the company's TRILOGY Phase 3 program evaluating lead drug candidate CaPre® (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia (HTG), a condition of elevated triglycerides (TGs) in the bloodstream that increases the risk of coronary artery disease and pancreatitis.

"We have initiated our pivotal Phase 3 program to demonstrate the effectiveness of CaPre to lower very high levels of triglycerides as well as to potentially improve patients' broader lipid profile, which could position our product as best in class in the marketplace," said Jan D'Alvise, president and CEO of Acasti Pharma. "We continue to execute on our timeline to obtain the topline data from TRILOGY by the end of 2019, which along with data from CaPre's two Phase 1 and two Phase 2 trials, will support our submission of a new drug application to the FDA."

The American Heart Association estimates that one-third of adults in the U.S. have elevated levels of TGs, including approximately 36 million people diagnosed with high HTG, and 3 to 4 million people diagnosed with severe HTG. Severe HTG 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.

Acasti believes that ongoing outcome studies, if positive, may greatly expand the omega-3 drug market in the U.S. to include a broader range of patients with high HTG (200 mg/dL - 499 mg/dL). These outcome trials, expected to report by the end of the third quarter of 2018 (REDUCE-IT trial sponsored by Amarin) and in 2019 (STRENGTH trial sponsored by AstraZeneca), are designed to evaluate the long-term cardiovascular benefits of lowering TGs with prescription drugs containing omega-3 fatty acids taken in addition to a statin. Additional clinical trials would likely be required for CaPre to also expand its label claims to the high TGs segment.

[Dariush Mozaffarian, M.D., Dr.P.H](#) is leading the TRILOGY program as the principal investigator. Dr. Mozaffarian is a board-certified cardiologist and epidemiologist and is the Jean Mayer Professor of Nutrition and Medicine, and the Dean of the Friedman School of Nutrition Science and Policy at Tufts University. His research focuses on the influence of lifestyle and diet on cardiometabolic health, and how changes to policies may improve health and wellness.

"Derived from krill oil, CaPre is an omega-3 phospholipid ester that we are investigating for the treatment of severe hypertriglyceridemia that may provide patients with a new treatment approach to reduce triglycerides while potentially modulating the other major lipids associated with cardiovascular disease risk," said Dr. Mozaffarian. "We are assessing in the Phase 3 trials whether CaPre can significantly reduce triglycerides and non-HDL cholesterol without increasing LDL-C and possibly increase levels of HDL-C."

In two [Phase 2 clinical trials](#) (COLT and TRIFECTA), CaPre significantly lowered TGs in patients with mild to severe HTG. CaPre also demonstrated no deleterious effect on LDL-C ("bad cholesterol"), unlike LOVAZA and EPANOVA, which have been shown to significantly increase LDL-C in patients with severe HTG. Excess LDL-C is undesirable because it accumulates in the walls of blood vessels, where it can cause blockages (atherosclerosis). In the Phase 2 trials, CaPre also reduced non-HDL-C (all cholesterol contained in the bloodstream except HDL-C), which is also considered to be a marker of cardiovascular disease. The COLT trial data showed a mean increase of 7.7% in HDL-C with CaPre at 4 grams per day, the same dose to be evaluated in the TRILOGY Phase 3 program. In both Phase 2 trials, CaPre was found to be safe and well tolerated at all doses tested.

Acasti engaged one of the biopharmaceutical industry's largest contract research organizations as a partner to conduct the TRILOGY Phase 3 program.

CaPre Phase 3 TRILOGY Program Design

TRILOGY, an acronym derived from "Phase 3 Studies of CaPre in Lowering Very High Triglycerides," is a double-blind, placebo-controlled, 26-week, two-trial Phase 3 clinical program designed to evaluate the safety and efficacy of CaPre in patients with severe HTG. TRILOGY 1 and TRILOGY 2 are running in parallel and will randomize a total of approximately 500 patients. The program is being conducted at approximately 150 sites in North America.

The primary endpoint of the identical trials is to determine the efficacy of CaPre 4 grams daily compared to placebo in lowering TG levels after 12 weeks of treatment, in subjects with fasting TG levels between 500 mg/dL and 1500 mg/dL. The safety and efficacy of CaPre will also be evaluated over 26 weeks of treatment. Numerous secondary endpoints will assess the effect of CaPre on patients' broader lipid profile and certain exploratory metabolic, glycemic diabetic markers, inflammatory and cardiovascular risk markers. Acasti expects to report topline results from the parallel trials by the end of 2019.

Additional information on the TRILOGY program can be found at www.clinicaltrials.gov, with the NCT Identifiers #03398005 and #03361501.

About [CaPre](#) (omega-3 phospholipid)

Acasti's prescription drug candidate, CaPre, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to treat severe hypertriglyceridemia, a metabolic condition that contributes to increased risk of cardiovascular disease and pancreatitis. Its omega-3s, principally eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), are 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").

About Acasti Pharma

Acasti Pharma is a biopharmaceutical innovator advancing a potentially best-in-class cardiovascular drug, CaPre (omega-3 phospholipid), for the treatment of hypertriglyceridemia, a chronic condition affecting an estimated one third of the U.S. population. The company's strategy is to initially develop and commercialize CaPre for the 3 to 4 million patients in the U.S. with severe hypertriglyceridemia. 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 make a positive impact on the major blood 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 www.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) accept responsibility for the adequacy or accuracy of this release.

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