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Acasti Pharma Achieves Planned Enrollment Targets for TRILOGY Phase 3 Trials of CaPre® in Patients with Severe Hypertriglyceridemia

LAVAL, Québec, Dec. 20, 2018 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti or the "Company") (NASDAQ: ACST – TSX-V: ACST), a biopharmaceutical innovator focused on the research, development and commercialization of its prescription drug candidate CaPre® (omega-3 phospholipid) for the treatment of severe hypertriglyceridemia (HTG), today announced it has reached the enrollment targets for its TRILOGY phase 3 trials. In total, over 1,450 patients have been enrolled at 150 clinical sites across the U.S., Canada and Mexico.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "We are pleased to report we have achieved our planned enrollment targets on schedule. Additionally, as of December 19, 2018, more than 60% of the required total of 500 patients for the two studies have been randomized. Additional patients may still be added to the TRILOGY program as needed early next year to achieve final randomization targets. We are further encouraged by the fact the drop-out rates have been well below expectation. As a result, we remain confident that we will complete these studies on schedule, and expect to report topline results before the end of calendar 2019."

Dr. Pierre Lemieux, CSO and COO of Acasti Pharma, further noted, "We are encouraged by the progress we are making with the TRILOGY Phase 3 trials. If our Phase 3 results replicate our Phase 2 data, CaPre has the potential to become best-in-class due to several potential clinical advantages. First, our prior studies of CaPre showed a significant reduction of triglyceride (TG) levels in patients with mild to severe HTG, and showed no safety concerns. Second, CaPre showed the potential to reduce LDL-C ("bad cholesterol"), in spite of the presence of DHA. Third, CaPre demonstrated the potential to increase high-density lipoprotein cholesterol (HDL-C) ("good cholesterol") at the therapeutic dose of 4 grams/day. Fourth, CaPre also showed the potential to reduce HbA1c, an important biomarker of long-term glucose control in patients with diabetes. And finally, unlike other competing products, CaPre does not require a fatty meal to improve bioavailability and absorption."

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 EPA and DHA, are either "free" or bound to phospholipids that allows for better absorption into the body. Acasti believes that EPA and

DHA are more efficiently transported by phospholipids sourced from krill oil than the EPA and DHA contained in fish oil that are transported either by triglycerides (as in dietary supplements) or as ethyl esters in other prescription omega-3 drugs, which must then undergo additional digestion before they are ready for transport in the bloodstream. Acasti's CaPre Phase 3 program is currently underway.

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. 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. The company is developing CaPre in a Phase 3 clinical program in patients with severe hypertriglyceridemia, a market that includes 3 to 4 million patients in the U.S. The addressable market may expand significantly if omega-3s demonstrate long-term cardiovascular benefits in on-going third party outcomes studies. Acasti may need to conduct at least one additional clinical trial to support FDA approval of a supplemental New Drug Application to expand CaPre's indications to this segment. Acasti's strategy is to commercialize CaPre in the U.S. and the company is pursuing development and distribution partnerships to market CaPre in major countries around the world. 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 information" within the meaning of Canadian securities laws and "forward-looking statements" within the meaning of U.S. federal securities laws (collectively, "forward-looking statements"). 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," "potential," "should," "may," "will," "plans," "continue" or other similar expressions 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. Forward-looking statements in this press release include, but are not limited to, information or statements about Acasti's strategy, future operations, prospects and the plans of management; Acasti's ability to conduct all required clinical and non-clinical trials for CaPre, including the timing and results of those trials; the timing and the outcome of licensing negotiations; CaPre's potential to become the "best-in-class" cardiovascular drug for treating severe Hypertriglyceridemia (HTG); CaPre's potential to increase HDL-C ("good cholesterol") at the therapeutic dose of 4 grams/day; CaPre's potential to reduce HbA1c, an important biomarker of long-term glucose control in patients with diabetes; Acasti's ability to commercially launch CaPre; and, Acasti's ability to fund its continued operations.

The forward-looking statements contained in this press release are expressly qualified in their entirety by this cautionary statement, the "Cautionary Note Regarding Forward-Looking

Information” section contained in Acasti’s latest annual report on Form 20-F and most recent management’s discussion and analysis (MD&A), which are 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. 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 assumptions and 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, including Acasti’s latest annual report on Form 20-F and most recent MD&A.

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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