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Acasti Pharma Provides Clinical and Market Update

TRILOGY phase 3 studies exceed 75% enrollment; on track to report topline results in 2019

LAVAL, Quebec, Sept. 18, 2018 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (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, today provided a clinical and market update.

Jan D’Alvise, president and CEO of Acasti Pharma, commented, “I am pleased to report we remain on track with our two TRILOGY Phase 3 studies, and expect to complete enrollment this year. As of today, we have exceeded 75% enrollment and 30% randomization at clinical sites across the U.S., Canada, and Mexico. We look forward to completing the studies on schedule and reporting topline results before the end of 2019.”

“We remain very encouraged by the outlook for CaPre. Prior to commencing our Phase 3 trials, CaPre was studied in four clinical trials totaling 773 patients, a substantial patient population. Based on the data in our earlier trials, CaPre showed a significant reduction of triglycerides (TG) and non-high density lipoprotein cholesterol (non-HDL-C) levels in the blood of patients with mild to severe HTG, and had no safety concerns. Unlike competitive prescription OM3 products, CaPre also showed the potential to reduce LDL-C (“bad cholesterol”) and increase high-density lipoprotein cholesterol (HDL-C), or “good” cholesterol, at the therapeutic dose of 4 grams/day. Patients with diabetes in our Phase 2 trials also showed a significant reduction of HbA1c, indicating that CaPre may improve glucose metabolism. These unique clinical benefits are a result of CaPre’s proprietary omega-3 (OM3) phospholipid formulation, which combines EPA and DHA, and delivers both of these OM3s important for heart health either bound to phospholipids or as free fatty acids – both forms are readily absorbed by the body. Consequently, patients taking CaPre can remain on their physician prescribed low fat diet and get full efficacy benefit. We believe these and other advantages set CaPre apart as potentially best-in-class.”

“The U.S. is the largest market for prescription OM3s with approximately 3 to 4 million patients diagnosed with severe hypertriglyceridemia and about 5 million scripts written each year. Two FDA approved prescription OM3s (VASCEPA and EPANOVA) are currently being tested in extensive cardiovascular outcome trials (REDUCE-IT and STRENGTH respectively). If these studies successfully prove that reducing triglycerides in HTG patients taking a prescription OM3 on top of a statin reduces residual cardiovascular risk, there is potential to expand the addressable market ten-fold to the roughly 36 million patients with high triglycerides (blood levels between 200 – 499 mg/dL) (The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease, 2011). While we are encouraged by the market expansion potential from these trials, it is also important to note

that CaPre is highly differentiated for many of the aforementioned reasons, and could overcome the shortcomings of existing prescription OM3s due to its unique composition, formulation and resulting clinical benefits. Given these advantages, we believe the potential of CaPre will remain significant, regardless of the outcome of these trials. As a result, Acasti may elect to conduct at least one post-approval clinical trial to support FDA approval of a supplemental New Drug Application to expand CaPre's indications to this segment."

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 outcomes studies (REDUCE-IT and STRENGTH). 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), 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.

Acasti Contact:

Jan D'Alvise
Chief Executive Officer
Tel: 450-686-4555
Email: info@acastipharma.com
www.acastipharma.com

U.S. Contact:

Crescendo Communications, LLC
Tel: 212-671-1020
Email: ACST@crescendo-ir.com



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