

Acasti Pharma Announces Publication of CaPre Pharmacokinetics Study in a Leading Peer-Reviewed Journal

Reinforces prior study results demonstrating proportional dose response and that bioavailability of CaPre is not meaningfully affected by the fat content of a meal

LAVAL, Québec, Nov. 07, 2019 (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 the publication as Articles in Press of a CaPre pharmacokinetics study, entitled, "Evaluation of OM3-PL/FFA Pharmacokinetics After Single and Multiple Oral Doses in Healthy Volunteers" in a leading peer-reviewed journal, Clinical Therapeutics. The study publication is available online and can be accessed at: [https://www.clinicaltherapeutics.com/article/S0149-2918\(19\)30499-0/fulltext](https://www.clinicaltherapeutics.com/article/S0149-2918(19)30499-0/fulltext) .

In this Phase I, open-label, randomized, multiple-dose, single-center, parallel-design study, 42 healthy volunteers received a single dose of CaPre (OM3-PL/FFA) at day 1, followed by multiple oral doses of 1, 2, and 4 grams per day for 14 days. At day 15, all subjects received a high fat breakfast.

Key findings included:

- CaPre was well tolerated in healthy subjects when administered as multiple oral doses of 1, 2, and 4 grams per day
- CaPre's PK parameters appeared to be approximately dose proportional over the 1-4 grams/day dose range
- The bioavailability of CaPre did not appear to be meaningfully affected by the fat content of the meal consumed before dose administration

Dr. Robert Hegele, Director of the Blackburn Cardiovascular Genetics Laboratory at Robarts Research Institute and co-author of the study, commented, "Although there are several approved prescription OM3 drugs for the treatment of severe HTG, there is need for a formulation with high bioavailability regardless of fat intake, since a low-fat diet is part of the management of patients with HTG. The study results for CaPre demonstrated greater exposure at higher doses, irrespective of fat content of the meal."

Pierre Lemieux, Ph.D., COO and CSO of Acasti, commented, "We are very pleased to have our study published in a leading peer-reviewed journal. This study further reinforces the favorable dose response reported in our prior clinical trials. This is important due to the fact patients randomized to CaPre in the TRILOGY trials all received 4 grams per day, compared

to our Phase 2 studies that included a range of doses from 1 gram, 2 gram and 4 grams per day. Moreover, exposure was unaffected by fat content of the meal. This is an important distinction as current prescription omega-3s on the market are bound to ethyl-esters, which require patients to take their omega-3s with a high fat meal for ideal absorption, despite the fact patients with high triglycerides are advised by physicians to follow a restricted low-fat diet.”

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, which 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. Clinically, the phospholipids may not only improve the absorption, distribution, and metabolism of omega-3s, but they may also decrease the synthesis of LDL cholesterol in the liver, impede or block cholesterol absorption, and stimulate lipid secretion from bile. In two Phase 2 studies, CaPre achieved a statistically significant reduction of triglycerides and non-HDL cholesterol levels in patients across the dyslipidemia spectrum from patients with mild to moderate hypertriglyceridemia (patients with TG blood levels between 200mg/dl and 500mg/dl) to patients with severe hypertriglyceridemia (those with TG levels above 500mg/dl). Furthermore, in the Phase 2 studies, CaPre demonstrated the potential to actually reduce LDL, or “bad cholesterol”, as well as the potential to increase HDL, or “good cholesterol”, especially at the therapeutic dose of 4 grams/day. The Phase 2 data also showed a significant reduction of HbA1c at a 4 gram dose, suggesting that due to its unique omega-3/phospholipid composition, CaPre may actually improve long-term glucose metabolism. Acasti’s TRILOGY 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,” “targeted” 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, CaPre’s potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo, 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.

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Source: Acasti Pharma, Inc.