

April 1, 2019



## **Acasti Pharma Announces Publication of CaPre Bioavailability Study in Leading Peer-Reviewed Journal**

*Further validates prior study results demonstrating that the bioavailability of CaPre is significantly better than LOVAZA when taken with a low-fat meal*

LAVAL, Québec, April 01, 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 of a CaPre® bioavailability study, entitled "A Single-dose, Comparative Bioavailability Study of a Formulation Containing OM3 as Phospholipid (PL) and Free Fatty Acid (FFA) to an Ethyl Ester (EE) Formulation in the Fasting and Fed States," which was published in the March 2019 issue of Journal of Clinical Therapeutics (Clinical Therapeutics 41 (2019) pp. 426-444), a leading peer-reviewed journal in the field of clinical pharmacology and therapeutics. The study publication is also available online at: [https://www.clinicaltherapeutics.com/article/S0149-2918\(19\)30055-4/fulltext](https://www.clinicaltherapeutics.com/article/S0149-2918(19)30055-4/fulltext).

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 or OM3-EE) in 56 healthy volunteers. Among subjects in the fasting state, CaPre demonstrated better bioavailability than LOVAZA, as measured by blood levels of EPA and DHA.

The article concluded: *"Among subjects in the fasted state, the test product (CaPre) demonstrated greater bioavailability of EPA and DHA in the form of free fatty acids and esterified to phospholipids as compared to OM3-EE (reference product). Bioavailability with OM3-EE was drastically reduced in the fasted state compared to administration with a high-fat meal. Since patients with severe HTG should adhere to a low-fat diet, these findings suggest preserved exposure, and perhaps retained efficacy, in patients taking OM3-PL/FFA in the fasted state or with a low-fat diet."*

Dr. Robert Hegele, Director of the Blackburn Cardiovascular Genetics Laboratory at Robarts Research Institute and co-author of the study, commented, "With the renewed interest in omega-3 fatty acids to reduce cardiovascular risk, it's important to evaluate similarities and differences between various preparations. This study shows that bioavailability of CaPre is less affected by dietary fat compared to another commonly used form of omega-3. This might be important for clinical use in treating patients with elevated blood lipids to prevent heart attacks and strokes."

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, which further validates the superior

bioavailability of CaPre when compared to the omega-3 ethyl ester drug, LOVAZA, in conditions which we believe are more relevant for patients with severe HTG. We also believe the unique combination of EPA, DHA and phospholipids in CaPre's composition contribute to CaPre's potential "trifecta effect," by: (a) lowering triglycerides; (b) reducing non-high-density lipoprotein cholesterol (non-HDL-C) levels including LDL-C ("bad cholesterol"); and (c) increasing high-density lipoprotein cholesterol (HDL-C) ("good cholesterol"). With high rates of obesity and diabetes fueling the number of patients with elevated triglycerides and cholesterol, CaPre could fill the need for a best-in-class omega-3 medication that addresses the full lipid profiles of these patients. We continue to make rapid progress on our TRILOGY Phase 3 trials, and based on current trends we remain on track to report topline results before the end of this year."

### **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 200 mg/dL [2.3 mmol/L] and 500 mg/dL [5.6 mmol/L]) to patients with severe hypertriglyceridemia (those with TG levels above 500 mg/dL [5.6 mmol/L]). 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](http://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, 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](http://www.sedar.com), on EDGAR at [www.sec.gov/edgar/shtml](http://www.sec.gov/edgar/shtml), and on the investor section of Acasti's website at [www.acastipharma.com](http://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](mailto:info@acastipharma.com)  
[www.acastipharma.com](http://www.acastipharma.com)

**Investor Contact:**

Crescendo Communications, LLC  
Tel: 212-671-1020  
Email: [ACST@crescendo-ir.com](mailto:ACST@crescendo-ir.com)



Source: Acasti Pharma, Inc.