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# **Acasti Pharma Provides Update On CaPre Phase 3 Development Program**

## **Outcome of the End-of-Phase 2 Meeting with the FDA**

### **Confirms Phase 3 Program is on Track to Start Late 2017**

LAVAL, QUEBEC -- (Marketwired) -- 03/30/17 -- Acasti Pharma Inc. (NASDAQ:ACST)(TSX VENTURE:ACST) today announced its plans to proceed with its Phase 3 development program for CaPre® (omega-3 phospholipid), following the company's recent end-of-Phase 2 meeting with the U.S. Food and Drug Administration. CaPre is a potentially best-in-class omega-3 drug derived of krill oil being developed for the treatment of patients with hypertriglyceridemia, a metabolic condition that contributes to the risk of cardiovascular disease and pancreatitis.

Acasti plans to conduct two pivotal, randomized, placebo controlled studies to evaluate the efficacy and safety of CaPre in patients with severe hypertriglyceridemia (very high triglyceride levels  $\geq 500$  mg/dL). The studies will evaluate the ability of CaPre to lower triglycerides from baseline in approximately 400 patients randomized to either CaPre 4g daily or placebo. The regulatory agency's feedback supports Acasti's plan to conduct two studies instead of one large study, potentially shortening the time to New Drug Application (NDA) submission.

"With the FDA's guidance, we've charted the course for our registration program for CaPre. This represents an important milestone in our aspiration to provide a differentiated omega-3 therapeutic for the large population of patients with hypertriglyceridemia," said Jan D'Alvise, president and CEO of Acasti Pharma. "We are also making excellent progress on completing the production of the CaPre clinical trial product in preparation for the anticipated initiation of the Phase 3 program in the second half of 2017."

Acasti's development program will be designed to satisfy the requirements of the 505(b)(2) regulatory pathway for a NDA. This program will allow Acasti to demonstrate CaPre's clinical benefits, while leveraging the substantial clinical and nonclinical safety data already available with LOVAZA (omega-3-acid ethyl esters), an already-approved omega-3 prescription drug.

CaPre is designed to modulate the unhealthy levels of the major lipids that can be associated with cardio-metabolic disease. In four clinical trials conducted to date, Acasti saw the following beneficial effects with CaPre:

- Significant reduction of triglycerides and non-high density lipoprotein cholesterol (non-HDL-C) levels in the blood of patients with mild to severe hypertriglyceridemia;
- No deleterious effect on low-density lipoprotein cholesterol, or "bad" cholesterol (LDL-C), and potential to reduce LDL-C;

- Potential to increase high-density lipoprotein cholesterol, or "good" cholesterol (HDL-C);
- Good bioavailability without significant food effect, important considerations for patients with metabolic disease who should be on a low fat diet and;
- An overall safety profile similar to that of currently marketed omega-3s, with the added potential for beneficial LDL-C effect.

### ***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 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.

### ***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 corporation's strategy is to initially develop and commercialize CaPre for the three to four 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](http://www.acastipharma.com).

### ***Forward Looking Statements***

Statements in this press release that are not statements of historical or current fact constitute "forward looking statements" and "forward-looking information" (collectively, "forward-looking statements") within the meaning of the U.S. securities laws and Canadian securities laws, including, without limitation, statements with respect to the proposed initiation of the Phase 3 development program for CaPre and the timing of such development program. 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. Certain important assumptions by Acasti in making forward-looking statements include, but are not limited to, Acasti's ability to obtain additional capital and financing as needed on favorable terms, Acasti's ability to take advantage of business opportunities in the pharmaceutical industry and the receipt of strategic partner support, and Acasti's estimate of the timeline and costs for its development programs not being affected by unforeseen events or circumstances. 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](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 [acastipharma.com](http://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 regulators. 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) accepts responsibility for the adequacy or accuracy of this release.

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