



## Acasti Provides Update on CaPre® Development Pathway

- | *Encouraging response from FDA on CaPre® clinical development*
- | *Seeking formal approval to commence bioavailability bridging study*

LAVAL, Quebec, Dec. 16, 2015 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**" or the "**Corporation**") (NASDAQ:ACST) (TSX-V:APO), an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, announces that it has received positive feedback from the US Food and Drug Administration (FDA) on the proposed development pathway for CaPre®.

"Recently, we received encouraging comments from the FDA based on our briefing package submission indicating that the 505(b)(2) pathway represents a course for regulatory review and approval, and that Acasti's plans for the bioavailability bridging study are viewed as sound," highlighted Pierre Lemieux, PhD, Acasti's Chief Operating Officer. "With this endorsement, Acasti will submit an amendment to its current Investigational New Drug (IND) application to commence a bridging study, while continuing to work closely with the FDA to ensure the Corporation is aligned with their views on CaPre® clinical development."

As previously announced, the 505(b)(2) approval pathway has been used by many other companies to secure approval for a New Drug Application (NDA). Acasti's regulatory and clinical experts believe such a strategy is best for CaPre®. The 505(b)(2) application also enables regulatory submission for a New Chemical Entity (NCE) approval when some part of the data application is derived from studies not conducted by the applicant. It allows Acasti to further optimize the advancement of CaPre®, including the Phase 3 protocol design, while also benefiting from the substantial clinical and nonclinical data already available with another FDA-approved omega-3 prescription drug. In addition, it should reduce expenses, accelerate the timing and streamline the overall development program required to support a NDA submission.

Based on the proposed 505(b)(2) regulatory pathway, Acasti is pursuing a pivotal bioavailability bridging study, comparing CaPre® and another FDA-approved omega-3 prescription drug as a means of establishing a scientific bridge between the two. This will help determine the feasibility of a 505(b)(2) regulatory pathway, while also optimizing the protocol design of a Phase 3 trial.

### **505(b)(2) Regulatory Pathway**

*The 505(b)(2) regulatory pathway is defined in The Federal Food Drug and Cosmetics Act as a New Drug Application (NDA) containing investigations of safety and effectiveness that are being relied upon for approval and were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. These applications differ from the typical NDA (described under Section 505(b)(1) of the Act), in that they allow a sponsor to rely, at least in part, on the FDA's findings of safety and/or effectiveness for a previously approved drug.*

### **About Acasti Pharma Inc.**

Acasti is an emerging biopharmaceutical company focused on the research, development and commercialization of new krill oil-based forms of omega-3 phospholipid therapies for the treatment and prevention of certain cardiometabolic disorders, in particular abnormalities in blood lipids, also known as dyslipidemia. Because krill feeds on phytoplankton (diatoms and dinoflagellates), it is a major source of phospholipids and polyunsaturated fatty acids ("PUFAs"), mainly eicosapentaenoic acid ("EPA") and docosahexaenoic acid ("DHA"), which are two types of omega-3 fatty acids well known to be beneficial for human health. CaPre®, currently Acasti's only prescription drug candidate, is a highly purified omega-3 phospholipid concentrate derived from krill oil and is being developed to help prevent and treat hypertriglyceridemia, which is a condition characterized by abnormally high levels of triglycerides in the bloodstream. ONEMIA®, a medical food and currently Acasti's only commercialized product, is a purified omega-3 phospholipid concentrate derived from krill oil with lower levels of phospholipids, EPA and DHA content than CaPre®.

### **Forward Looking Statements**

*Statements in this press release that are not statements of historical or current fact constitute "forward-looking statements" within the meaning of the U.S. securities laws and Canadian securities laws. 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," "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 commissions. 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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