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FDA Clears Acasti's Investigational New Drug Submission to Conduct PK Trial

LAVAL, Quebec, Jan. 9, 2014 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (**Acasti**" or the **"Corporation"**) (Nasdaq:ACST) (TSX-V:APO), an emerging biopharmaceutical company, announces that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) submission to initiate a Pharmacokinetic (PK) trial of CaPre[®] in the U.S., having found no objections with the PK trial design, protocol, or safety profile of CaPre[®]. Following the clearance, Acasti engaged Quintiles, the world's largest provider of biopharmaceutical development and commercial outsourcing services, to conduct its PK study.

"Today's announcement takes us another step towards securing regulatory approval to distribute and market CaPre[®] as a prescription drug in the U.S.," highlighted Mr. Henri Harland, President and CEO of Acasti. "With this achievement, we are moving forward as planned with our research and clinical development programs for our investigational new drug CaPre[®]."

The PK trial is an open-label, randomized, multiple-dose, single-center, parallel-design study that will evaluate blood profiles and bioavailability of omega-3 phospholipids on 42 healthy volunteers taking single and multiple daily oral doses of 1, 2 and 4 grams of CaPre[®].

[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

Certain statements included in this press release may be considered forward-looking information within the meaning of Canadian securities laws and forward-looking statements within the meaning of U.S. federal securities laws, both of which we refer to as 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," "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 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. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by Acasti in its public securities filings available at www.sedar.com and www.sec.gov/edgar.shtml, actual events may differ materially from current expectations. Except as required by law, Acasti disclaims any intention or obligation to update or revise any forward-looking statements.

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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