

# Acasti Pharma Awarded Notice of Allowance for Additional Composition of Matter and Method of Use Patents in the United States and Mexico

Patent upheld in Japan following opposition filings and subsequently allowed

Completes TRILOGY 1 audits and accelerates plans to submit FDA meeting request by the end of March

LAVAL, Québec, March 11, 2020 (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, today announced that it has received a Notice of Allowance for an additional composition of matter and method of use patent from the US Patent and Trademark Office (USPTO), the 4th patent to be awarded in the U.S., and a Notice of Allowance for a composition of matter and method of use patent awarded by the Mexican Patent Office, the 3rd patent to be awarded in Mexico. These new patents broaden the Company's existing claims to include any composition containing EPA and DHA where at least 50% of the composition consists of phospholipids. These new patents further strengthen the intellectual property position of CaPre. In addition, Acasti also received a favorable decision issued by the Japan Patent Office following an opposition proceeding filed by a third party against its divisional application, confirming its validity. This decision resulted in the allowance of Acasti's second major patent in Japan.

"The United States and Mexico represent important markets for Acasti, given the high prevalence of hypertriglyceridemia and the need for an effective, safe and well-absorbing omega-3 therapeutic for the treatment of cardiovascular-related diseases. Furthermore, these patents strengthen the Company's strategic position in these important markets, which could support valuable commercial opportunities in the future. In addition, Acasti's success in upholding its patent in Japan is a yet another confirmation of the strength of our claims and IP portfolio," said Pierre Lemieux, PhD, Acasti's Chief Operating Officer and Chief Scientific Officer.

Jan D'Alvise, president and CEO of Acasti Pharma, commented, "We have completed the clinical site and central lab audits of the TRILOGY 1 data, including additional post-hoc analyses. As a result, I am pleased to report that we now expect to submit our FDA meeting request by the end of March. We look forward to reporting further developments, including an update on a meeting date as soon as it has been set."

**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 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 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 outcomes studies (REDUCE-IT and STRENGTH). Acasti may need to conduct at least one additional clinical trial 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 <a href="https://www.acastipharma.com">www.acastipharma.com</a>.

# **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" 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; and CaPre's potential to become the "best-in-class" cardiovascular drug for treating severe Hypertriglyceridemia (HTG).

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 <a href="www.sedar.com">www.sedar.com</a>. on EDGAR at <a href="www.sec.gov/edgar/shtml">www.sec.gov/edgar/shtml</a>, and on the investor section of Acasti's website at <a href="www.acastipharma.com">www.acastipharma.com</a>. 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.

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