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Acasti Pharma Submits FDA Meeting Request on Schedule, and FDA Meeting Expected in the Second Half of June

LAVAL, Québec, April 01, 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 filed its meeting request with the Food and Drug Administration (FDA). The meeting is intended to discuss TRILOGY 1 data, and gain alignment with the FDA on the interpretation of the results. The Company will also seek the FDA’s input on Acasti’s proposed revisions to the pre-specified TRILOGY 2 statistical analysis plan (SAP), and explore and agree on a plan for pooling the data from TRILOGY 1 and TRILOGY 2 in support of an NDA filing. Acasti remains blinded to the TRILOGY2 results, and intends to update the statistical analysis plan (SAP) with these revisions if the FDA agrees. As previously noted, upon submission of the meeting request, Acasti anticipates meeting with the FDA in the second half of June.

Jan D’Alvise, President and CEO of Acasti Pharma, commented, “We are pleased to have completed the TRILOGY 1 clinical site and central lab audits as planned, including additional post-hoc analyses, and to have submitted our meeting request to the FDA on schedule. We believe the FDA meeting will provide essential guidance as we prepare to unblind and conduct the topline analysis of the TRILOGY 2 data. We look forward to meeting with the FDA and providing further updates as they unfold.”

Annual Stock Option Grants

Acasti also announced today the annual grant of stock options to its employees, executives and directors, and the amendment of its stock option plan (the “Stock Option Plan”). The stock options were granted by the Board of Directors as part of the Company’s annual performance review in accordance with the Company’s Long-Term Incentive Program (LTIP). On March 31, 2020, an aggregate of 3,836,000 stock options were granted to certain employees, executives and directors of the Company under the Company’s Stock Option Plan. Subject to the terms and conditions of the Stock Option Plan, options granted to directors will vest in equal monthly installments over a period of 12 months and options granted to executives and employees will vest in equal quarterly installments over a period of 36 months. Each option will entitle the holder to purchase one common share of Acasti at a price of CDN$0.53, until March 31, 2030.

Subject to the approvals of the TSX Venture Exchange and of shareholders at the Company’s next annual and special meeting, on March 31, 2020, the Board of Directors amended the Stock Option Plan in order to reduce the minimum vesting period applicable for grants to directors from 18 months on a quarterly basis to 12 months on a monthly basis.

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 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" 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; CaPre's potential to become the "best-in-class" cardiovascular drug for treating severe Hypertriglyceridemia (HTG); and the timing and outcome of our requested meeting with the FDA.

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, on EDGAR at www.sec.gov/edgar/shtml, and *on the investor section of Acasti's website at 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.

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