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Acasti Pharma Partners with Aker BioMarine to Supply Krill Oil for CaPre®

Agreement provides Acasti long-term supply of raw krill oil through commercialization

LAVAL, Québec, Nov. 04, 2019 (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 partnered with Aker BioMarine to deliver krill oil to Acasti, under a two-year, fixed price supply agreement.

Raw Krill Oil (RKO) is the starting material used by Acasti to make CaPre, which is then further processed via a series of complex and proprietary extraction and purification manufacturing steps to produce the drug substance for CaPre. This agreement is intended to ensure an adequate krill oil supply to meet Acasti's anticipated raw material needs through at least mid-2021, including scale-up of production to build future inventory for commercial launch. Furthermore, the parties have agreed to contemplate future commercial collaborations.

"We have built a state-of-the-art manufacturing operation for CaPre, and it is important for us to continue to maintain long-term relationships with the highest quality suppliers across the entire supply chain, in order to ensure continuous operations and delivery of CaPre according to plan," said Pierre Lemieux, Ph.D. and Acasti's COO/CSO. "Aker BioMarine produces high quality krill oil, which is sustainably harvested and has been certified by the Marine Stewardship Council (MSC). This supply agreement secures a reliable source of high quality starting material for CaPre, which we expect will meet our near-term commercial growth aspirations. In addition, we look forward to collaborating on future projects together."

"Acasti, with its novel drug product CaPre, represents an exciting growth opportunity for our two organizations," said Tim de Haas, EVP Human Health & Nutrition, Aker BioMarine. "We are pleased to partner with Acasti to support commercialization of the first ever, krill oil-based, prescription drug product, which we believe has the potential to become the best-in-class omega-3 therapeutic for the management of cardiometabolic disorders. We look forward to working with their team on future supply initiatives."

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 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. 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. 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 third party outcomes studies. Acasti may need to conduct at least one additional clinical trial to support FDA approval of a supplemental New Drug Application 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.

About Aker BioMarine

Aker BioMarine is a biotech innovator and Antarctic krill-harvesting company, dedicated to improving human and planetary health. The company develops krill-based ingredients for nutraceutical, aquaculture, and animal feed applications. The company’s fully transparent value chain stretches from sustainable krill harvesting in pristine Antarctic waters through its Montevideo logistics hub, Houston production plant, and all the way to customers around the world. To learn more about Aker BioMarine, please visit the web site www.akerbiomarine.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,” “targeted” 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; the timing and the outcome of licensing negotiations; CaPre’s potential to become the “best-in-class” cardiovascular drug for treating severe Hypertriglyceridemia (HTG), Acasti’s ability to commercially launch CaPre, CaPre’s potential to meet or exceed the target primary endpoint of reducing triglycerides by 20% compared to placebo, and Acasti’s ability to fund its continued operations.

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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