September 22, 2021

Acasti Pharma Provides Update Following Acquisition of Grace Therapeutics and Regains Compliance with Nasdaq Listing Standards

LAVAL, Québec, Sept. 22, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), today provided a business update and announced that the Nasdaq Stock Market (“Nasdaq”) has confirmed to Acasti that the Company has regained compliance with Nasdaq’s minimum bid price requirement.

Jan D’Alvise, President and Chief Executive Officer of Acasti Pharma, commented, “We are pleased to have regained compliance with the listing requirements for Nasdaq, and are laser focused on the integration of Grace Therapeutics, which is progressing seamlessly. We could not be more excited by the outlook for the business and are working aggressively to advance our clinical pipeline of late-stage drug candidates focused on rare diseases that address significant markets with unmet medical needs. We believe our approach of customizing the formulation of marketed drugs in new ways—backed by more than 40 granted and patents pending in various jurisdictions—significantly de-risks our clinical programs. Specifically, these drug candidates are designed to achieve faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery. Our confidence is further reinforced by the fact that all three of our lead programs have received Orphan Drug Designation from the U.S. Food & Drug Administration, which offers a number of regulatory, cost and timing benefits. We look forward to providing continual updates on our clinical and regulatory progress in the weeks and months ahead.”

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery capability and technologies addressing rare and orphan diseases. Acasti’s novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery—all which could help to increase treatment compliance and improve patient outcomes.

Acasti’s three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States and protection by over 40 granted and pending patents. The lead assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), a rare and life-threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily impacts children causing severe disability,

for which no treatment currently exists; and (iii) GTX-101, a topical spray, targeting Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years. For more information, please visit: https://www.acastipharma.com/en.

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 the U.S. Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (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 labelled 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.

These forward-looking statements are based upon Acasti's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions and pre-clinical and clinical trials; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments, and (v) the effects of COVID-19 on clinical programs and business operations. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Acasti from time to time with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Acasti undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Neither NASDAQ, the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

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