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Acasti Pharma Awarded Composition-of-Matter Patents for GTX-101 in Europe, China and Mexico and for GTX-102 in Japan

Patents strengthen Acasti's IP portfolio and provide protection through 2036 and 2037, respectively

LAVAL, Québec, Oct. 06, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST), today announces that the European Patent Office, Chinese Patent Office and the Mexican Patent Office have issued composition of matter patents for GTX-101, a novel bio-adhesive film forming topical spray formulation of bupivacaine for the treatment of Postherpetic Neuralgia (PHN). PHN is 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. GTX-101 could provide significant benefits over the current standard of care including greater convenience, faster onset of action and longer duration of pain relief. The granted patents are valid until 2036.

In addition, the Japanese Patent Office has granted a composition of matter patent for GTX-102, a novel, easy-to-use oral mucosal spray formulation of betamethasone, intended to improve neurological symptoms of Ataxia-telangiectasia (A-T). A-T is a progressive, neurodegenerative genetic disease that primarily affects children causing severe physical disability, for which no treatment currently exists. The granted patent is valid until 2037.

Jan D'Alvise, Chief Executive Officer of Acasti, stated, "These latest patents are important additions to our intellectual property portfolio, expanding product protection to additional important international markets as we continue to progress these drug candidates through clinical studies. We believe these granted composition of matter patents further support the commercial potential of GTX-101 and GTX-102. Both drug candidates have already received Orphan Drug Designation from the FDA and could address important underserved global markets. The goal of these proprietary formulations is to improve the quality of care and patient outcomes by providing significant efficacy, safety and convenience benefits including ease of use, faster onset of action and extended relief."

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery technologies and drug candidates 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 additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical 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 affects children, causing severe disability, and 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 containing 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.

The forward-looking statements in this press release 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 of the PK bridging study for GTX-104 and Acasti's other 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 list 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 Securities and Exchange Commission. 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, except as required by applicable securities laws.

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.

Acasti Contact:
Jan D'Alvise
Chief Executive Officer
Tel: 450-686-4555
Email: info@acastipharma.com
www.acastipharma.com

Investor Contact:
Crescendo Communications, LLC
Tel: 212-671-1020
Email: ACST@crescendo-ir.com

Media Contact :
Jules Abraham
JQA Partners, Inc.
Tel: 917-885-7378
Email: jabraham@jqapartners.com

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