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Acasti Pharma Announces the Issuance of Additional Patents for GTX-104 and GTX-101

LAVAL, Québec, June 14, 2022 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), today announced that three composition of matter patents for GTX-104 were issued by The United States Patent and Trademark Office, the Japanese Patent Office, and the Australian Patent Office. Additionally, one new patent for GTX-104 was awarded by the Indian Patent Office. These granted patents are all valid until 2037.

GTX-104 is a novel formulation of nimodipine for IV infusion to treat patients suffering from Subarachnoid Hemorrhage (SAH), which is caused by a ruptured aneurysm and is estimated to affect about 110,000 patients per year, in the US and Europe. Acasti recently reported positive results for a pharmacokinetic (PK) study, with intravenous GTX-104 meeting all endpoints. Acasti is now working with the U.S. FDA to commence a Phase 3 study on GTX-104, which is expected to be the final step required to seek regulatory approval.

In addition, the Canadian Intellectual Property Office has issued a notice of allowance for a composition of matter patent for GTX-101, a topical spray of bupivacaine targeting 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. The granted patent is valid until 2036.

Jan D’Alvise, Chief Executive Officer of Acasti, stated, “We are pleased to report that our progress in the clinic is being matched by our progress protecting our intellectual property, both in North America and internationally. We are happy to highlight that we now hold 5 U.S. patents for GTX-104.”

“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 and we are pleased to see that we have additional IP coverage in Canada. We expect that a single-dose clinical trial will be launched soon to study the PK profile of GTX-101 in healthy volunteers,” D’Alvise concluded.

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," "estimates," "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 of the planned Phase 3 safety study for GTX-104 and Acasti's other pre-clinical and clinical trials; (ii) regulatory requirements or developments and the outcome of meetings with the FDA; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; (v) costs associated with Acasti's clinical trials and (vi) 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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