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Acasti Pharma Announces Initiation of Pharmacokinetic Bridging Study for GTX-104, the Company's Lead Drug Candidate for the Treatment of Subarachnoid Hemorrhage

Study expected to be completed in the first half of 2022, with the goal to commence the Phase 3 safety study in the second half of 2022

LAVAL, Québec, Sept. 27, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST), today announces the initiation of its planned pharmacokinetic (PK) bridging study to evaluate the relative bioavailability of intravenous (IV) GTX-104 compared to currently marketed oral nimodipine capsules in 50 healthy subjects. The PK study is the next required step in the proposed 505(b)(2) regulatory pathway for GTX-104.

Results from this study are expected in the first half of calendar 2022, and after review with the U.S. Food & Drug Administration (FDA), will help to determine the final design of the Company's planned Phase 3 safety study for GTX-104 in Subarachnoid Hemorrhage (SAH) patients. Assuming the PK study and related FDA review progress as planned, the Company expects to begin the Phase 3 study during the second half of 2022. GTX-104 is a novel IV nimodipine infusion being developed to treat SAH, which is a central nervous system condition that causes acute bleeding on the brain and requires immediate medical attention to prevent long-term disability or death. GTX-104 has been granted Orphan Drug Designation by the FDA, which could provide Acasti with seven years of market exclusivity, tax incentives and other economic benefits.

Jan D'Alvise, Chief Executive Officer of Acasti, stated, "We are rapidly advancing our clinical pipeline and are proud to have already initiated this PK bridging study of GTX-104 in the short time since completing our acquisition of Grace Therapeutics at the end of August. This latest study follows an earlier safety and dose-escalation crossover study conducted by Grace, which reported encouraging results."

"We believe GTX-104 has the potential to provide improved bioavailability and lower intra-subject variability compared to oral capsules, which could translate into better blood pressure control in these critically ill patients. Moreover, it could provide a more convenient dosing schedule that would be easier to administer to patients who are unconscious. SAH is a devastating condition that afflicts more than 50,000 patients per year in the United States and is one of the most expensive acute conditions to treat. As a result, we believe GTX-104, through our unique formulation, has the potential to address a sizable market opportunity with a significant unmet medical need," D'Alvise concluded.

The PK bridging study is a single center, randomized, two-period crossover study in 50 healthy subjects. The primary objective of the study is to evaluate the relative bioavailability of GTX-104, and the secondary objective of the study is to assess the safety and tolerability of GTX-104, compared to nimodipine oral capsules, the current standard of care.

Per the study protocol, subjects will be randomly assigned in a 1:1 ratio to one of two treatment sequences: AB or BA, where Treatment A and Treatment B are as follows:

- Treatment A: GTX-104 Nimodipine IV will be administered by infusion over 72 hours.
- Treatment B: Nimodipine capsules will be administered orally with 240 mL of water at a dose level of 60 mg (two 30 mg capsules) every 4 hours for 72 hours.

Safety assessments will be collected throughout the study and will include treatment-emergent adverse events, serious adverse events, electrocardiograms, clinical laboratory evaluations, physical examinations and resting vital signs (including blood pressure). Per the study protocol, healthy subjects will be admitted to the clinical research unit (CRU) on the day prior to dosing and will remain domiciled in the CRU for the duration of each study period.

About SAH
SAH is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is rupture of an aneurysm. The result is a relatively uncommon type of stroke that accounts for about one-in-twenty (5%) of all strokes and has an incidence of six per 100,000 person years (Becske, 2018).

In contrast to more common types of stroke in elderly individuals, SAH often occurs at a relatively young age, with half the affected patients being younger than 60 years (Becske, 2018). Particularly devastating for patients younger than 45, approximately 10 to 15% of aneurysmal SAH (aSAH) patients die before reaching the hospital (Rinkel, 2016), and those who survive the initial hours post hemorrhage are admitted or transferred to tertiary neurointensive care centers to manage the high risk of complications, including rebleeding and delayed cerebral ischemia (DCI). Systemic manifestations affecting cardiovascular, pulmonary, and renal function are common, and often complicate the management of DCI. Approximately 70% of aSAH patients experience death or dependence, and half die within one month after the hemorrhage. Of those who survive the initial month, half remain permanently dependent on someone else to maintain daily living (Becske, 2018).

About GTX-104
GTX-104 is a clinical stage, novel nanoparticle formulation of nimodipine being developed for IV infusion in SAH patients. It incorporates surfactant micelles as the drug carrier to solubilize nimodipine. This nimodipine injectable formulation is comprised of a nimodipine base, an effective amount of a hydrophilic surfactant, and a pharmaceutically acceptable carrier for injection. GTX-104 is an aqueous solution substantially free of organic solvents, such that the nimodipine is contained in a concentrated injection solution, suspension, emulsion or complex as a micelle, a colloidal particle or an inclusion complex, and the formulation is stable and clear. The addressable market in the United States for GTX-104 is estimated to be about $300 million based on market research conducted for Grace by Fletcher Spaght.

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.

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