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Acasti Announces WuXi Clinical as CRO to Conduct STRIVE-ON Pivotal Phase 3 Safety Trial for GTX-104 in aSAH Patients

STRIVE-ON is a pivotal Phase 3 trial of GTX-104 to evaluate its comparable safety and tolerability profile relative to oral nimodipine in patients hospitalized with aSAH

LAVAL, QB, July 10, 2023 /PRNewswire/ -- Acasti Pharma Inc. (Nasdaq: ACST) ("Acasti" or the "Company"), a late-stage, biopharma company advancing GTX-104, today announced WuXi Clinical Development, Inc. ("WuXi Clinical"), a wholly owned subsidiary of WuXi AppTec, a global Contract Research Organization (CRO), will conduct Acasti's STRIVE-ON Phase 3 safety trial for GTX-104. GTX-104 is Acasti's novel, injectable nimodipine formulation for intravenous infusion (IV) that addresses high, unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH). STRIVE-ON (Safety, Tolerability, Randomized, IV and Oral Nimodipine) will evaluate GTX-104's comparable safety and tolerability profile relative to oral nimodipine in patients hospitalized with aSAH.

"WuXi Clinical is a leader in the CRO industry with a strong track record in successfully helping pharmaceutical companies develop innovative therapies," said Prashant Kohli, CEO of Acasti. "Importantly, they are one of the few CROs with significant experience in aSAH and rare diseases, making them the ideal partner for conducting the STRIVE-ON Phase 3 safety trial for GTX-104."

Over the past few months, Acasti and WuXi Clinical have been conducting preparatory work in advance of Acasti's recent alignment with the U.S. Food and Drug Administration (FDA) on the protocol for its pivotal Phase 3 trial of GTX-104. In addition, the FDA also provided Acasti guidance for a potential GTX-104 New Drug Application (NDA) package. Acasti is anticipating dosing the first patient in the fourth calendar quarter of 2023 and a potential NDA submission in the first half of calendar 2025.

"We are honored and pleased that Acasti has selected WuXi Clinical as its CRO partner to continue the clinical development of GTX-104. We appreciate the partnership, and our dedicated team is looking forward to assisting the Acasti team to advance GTX-104," says Steven Nelson, Vice President of Global Clinical Operations at WuXi Clinical.

About the STRIVE-ON Phase 3 Safety Trial

STRIVE-ON will be a prospective, open-label, randomized (1:1 ratio), parallel group trial of GTX-104 compared with oral nimodipine, in patients hospitalized for aSAH. Key trial design features include:

- Approximately 100 patients are expected to be enrolled at an estimated 25 hospitals in the U.S.
- The primary endpoint is safety and will be measured as comparative adverse events, including hypotension, between the two groups.
- GTX-104 will be administered as a continuous IV infusion of 0.15 mg/hour, and a 30-minute IV bolus of 4 mg every 4 hours. Oral nimodipine will be administered as 60 mg (two 30 mg capsules) every 4 hours.
- Both groups will receive their assigned GTX-104 or oral nimodipine for up to 21 consecutive days and will be evaluated from commencement of patient treatment through a 90-day follow-up period.

About WuXi Clinical Development

WuXi Clinical Development Inc., a wholly owned subsidiary of WuXi AppTec, is a global Contract Research Organization (CRO) providing a comprehensive range of services in clinical development. WuXi Clinical Development Inc. provides Phase I to Phase IV research & Bioequivalence studies for pharmaceuticals, biologics, and medical devices. With expertise spanning across all major therapeutic areas, WuXi Clinical Development Inc. delivers the unique blend of an experienced team combined with data-driven insights and responsiveness for better outcomes. WuXi Clinical Development Inc.'s forward-thinking approach has allowed it to accelerate a variety of clinical projects ranging from first-in-human products to marketed drugs and devices.

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH 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 the rupture of an aneurysm. Approximately 70% of aSAH patients experience death or dependence, and more than 30% die within one month of hemorrhage. Approximately 50,000 patients in the United States are affected by aSAH per year, based on market research.

About GTX-104

GTX-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous infusion (IV) in aSAH patients to address significant unmet medical needs. The unique nanoparticle technology of GTX-104 facilitates aqueous formulation of insoluble nimodipine for a standard peripheral IV infusion.

GTX-104 provides a convenient IV delivery of nimodipine in the Intensive Care Unit potentially eliminating the need for nasogastric tube administration in unconscious or dysphagic patients. Intravenous delivery of GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been administered in over 150 healthy volunteers and was well tolerated with significantly lower inter- and intra-subject pharmacokinetic variability compared to oral nimodipine. The

addressable market in the United States for GTX-104 is estimated to be about $300 million, based on market research.

About Acasti

Acasti is a late-stage biopharma company with 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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides 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 asset, GTX-104, is an intravenous infusion targeting aneurysmal Subarachnoid Hemorrhage (aSAH), 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.

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 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, and "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Such forward looking statements involve known and unknown risks, uncertainties, and other 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," "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. The forward-looking statements in this press release, including statements regarding the timing of the planned initiation of the Company's STRIVE-ON trial, anticipated NDA submission with the FDA, GTX-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated trial design of STRIVE-ON 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; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations. 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 are filed by Acasti from

time to time with the Securities and Exchange Commission and Canadian securities regulators. 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. NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

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