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Grace Therapeutics Announces Results From Pivotal Phase 3 STRIVE-ON Safety Trial of GTx-104 in aSAH

Trial Met the Primary Endpoint and Provides Evidence of GTx-104 Clinical Benefit Compared to Orally Administered Nimodipine

New Drug Application (NDA) Submission Expected in the First Half of 2025

PRINCETON, N.J., Feb. 10, 2025 (GLOBE NEWSWIRE) -- Grace Therapeutics, Inc. (Nasdaq: GRCE), formerly Acasti Pharma Inc. (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, a clinical-stage, novel, injectable formulation of nimodipine being developed for IV infusion to address significant unmet medical needs in aneurysmal Subarachnoid Hemorrhage (aSAH) patients, today announced that its Phase 3 STRIVE-ON safety trial (the STRIVE-ON trial–NCT05995405) met its primary endpoint and provides evidence of clinical benefit when compared to orally administered nimodipine.

The STRIVE-ON trial was a prospective, randomized open-label trial of GTx-104 compared with oral nimodipine in patients hospitalized with aSAH. 50 patients were administered GTx-104 and 52 patients received oral nimodipine. The primary endpoint was the number of patients with at least one episode of clinically significant hypotension reasonably considered to be caused by the drug, and additional endpoints included safety, clinical, and pharmacoeconomic outcomes. Each patient was evaluated for up to 90 days inclusive of the 21-day treatment period. There was a higher proportion of the most severe cases of aSAH (Hunt & Hess Grade V) with the worst prognosis in the GTx-104 arm (8%) compared to the oral nimodipine arm (2%).

The trial met its primary endpoint, with patients receiving GTx-104 observed to have a 19% reduction in at least one incidence of clinically significant hypotension compared to oral nimodipine (28% versus 35%). Other measures also favored or were comparable to GTx-104, including:

- 54% of patients who received GTx-104 had a relative dose intensity (RDI) of 95% or higher of the prescribed dose compared to only 8% on oral nimodipine.
- 29% relative increase in the number of patients receiving GTx-104 compared to oral nimodipine with favorable outcomes at 90 days follow up on the modified Rankin scale. Quality of life as measured by EQ-5D-3L also favored patients receiving GTx-104 versus oral nimodipine.
- Fewer intensive care unit (ICU) readmissions, ICU days, and ventilator days for patients receiving GTx-104 versus oral nimodipine.
- Adverse events were comparable between the two arms and no new safety issues were identified with patients receiving GTx-104. All deaths in both arms of the trial were

due to severity of the patient's underlying disease. There were eight deaths on the GTx-104 arm compared to four deaths on the oral nimodipine arm. The survival status of one patient on the oral nimodipine arm was unknown. No deaths were determined to be related to GTx-104 or oral nimodipine.

"We are thrilled that the STRIVE-ON trial results have exceeded our expectations and demonstrated improvements in clinical outcomes of these patients," said Prashant Kohli, CEO of Grace Therapeutics. "Importantly, the data provide both medical and pharmacoeconomic evidence of the potential benefit of GTx-104 in aSAH patients. We look forward to engaging with the FDA on these data, and we intend to submit our NDA in the first half of this calendar year."

"The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe these results point to a very promising role for GTx-104 as a potential breakthrough for the care of aSAH patients," said Dr. Loch MacDonald, Chief Medical Officer. "Although STRIVE-ON was not designed or powered to demonstrate efficacy, the data provide support for improvements in both clinical and patient reported outcomes. It is very gratifying to see our years of work on this formulation validated by the results of our STRIVE-ON trial."

"The topline data from the STRIVE-ON trial show that intravenous GTx-104 has the potential to reduce hypotension compared to orally administered nimodipine," said Dr. H Alex Choi, Professor of Neurology and Neurosurgery at UTHealth Houston / McGovern Medical School and a member of the Grace Scientific Advisory Board. "Nimodipine is an effective neuroprotective agent. The RDI data show that the IV formulation allows patients to receive more of this powerful medication with fewer hypotensive side effects. Compared to oral nimodipine, the ability to deliver adequate doses of nimodipine in the IV formulation translated into improvements in ICU length of stay, reduction in the need for mechanical ventilation and of ICU readmissions. These data provide a compelling case for GTx-104 as an alternative for oral nimodipine in hospital pharmacies should it be approved by the FDA."

KOL Event on aneurysmal Subarachnoid Hemorrhage (aSAH)

Grace Therapeutics hosted a Key Opinion Leader event in November 2024 featuring Abhishek Ray, MD (University Hospitals) and Andrew Webb, PharmD, BCCCP (Massachusetts General Hospital), who discussed the high unmet medical need and current treatment landscape for patients suffering aSAH.

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 in the brain. The result is a relatively uncommon type of stroke (aSAH) that accounts for about 5% of all strokes and an estimated 42,500 U.S. hospital treated patients.

About GTx-104

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for IV infusion 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.

About Grace Therapeutics

Grace Therapeutics, Inc. (Grace Therapeutics or the Company) (formerly Acasti Pharma Inc.) is a late-stage biopharma company with drug candidates addressing rare and orphan diseases. Grace Therapeutics' 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. Grace Therapeutic'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. Grace Therapeutics' 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. In February 2025, Grace Therapeutics announced that its Phase 3 STRIVE-ON safety trial for GTx-104 met its primary endpoint and provided evidence of clinical benefit over orally administered nimodipine.

For more information, please visit: www.gracetx.com

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 Grace Therapeutics 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 future prospects of the Company's GTx-104 drug candidate, the timing of the Company's anticipated NDA submission for GTx-104, GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, GTx-104's potential to be administered to improve

the management of hypotension in patients with aSAH, the ability of GTx-104 to achieve a pharmacokinetic and safety profile similar to the oral form of nimodipine, GTx-104's potential to achieve pharmacoeconomic benefit over the oral form of nimodipine, GTx-104's commercial prospects, the future prospects of the Company's GTx-102 drug candidate, GTx-102's potential to provide clinical benefits to decrease symptoms associated with Ataxia Telangiectasia, GTx-102's potential ease of drug administration, the timing and outcomes of a Phase 3 efficacy and safety study for GTx-102, the timing of an NDA filing for GTx-102, the size of the addressable market for GTx-104 and GTx 102, and any future patent and other intellectual property filings made by the Company for new developments are based upon Grace Therapeutics' 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 Phase 3 STRIVE-ON safety trial for GTx-104; (ii) regulatory requirements or developments and the outcome and timing of the proposed NDA 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 Grace Therapeutics' 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 the "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2024, Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024, the Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 and other documents that have been and will be filed by Grace Therapeutics 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. Grace Therapeutics 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.

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