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Grace Therapeutics Pivotal Phase 3 STRIVE-ON Safety Trial Presented at 2025 Neurocritical Care Annual Meeting

Presentation Highlighted Data Supporting Clinical Benefit of GTx-104 Compared to Orally Administered Nimodipine in the Treatment of aneurysmal Subarachnoid Hemorrhage (aSAH)

PRINCETON, N.J., Sept. 22, 2025 (GLOBE NEWSWIRE) -- Grace Therapeutics, Inc. (Nasdaq: GRCE) (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, a clinical-stage, novel, injectable formulation of nimodipine being developed for I.V. infusion to address significant unmet medical needs in aSAH patients, today announced that results from its Pivotal Phase 3 STRIVE-ON Safety Trial of GTx-104 in aSAH (the STRIVE-ON trial–NCT05995405) were presented at the *2025 Neurocritical Care Society* annual meeting, held in Montreal, Quebec, Canada September 18-21, 2025.

In an oral presentation titled *Safety and Tolerability of GTx-104 (Nimodipine Injection for I.V. Infusion) Compared with Oral Nimodipine in Patients with Aneurysmal Subarachnoid Hemorrhage: a Prospective, Randomized Trial,* Dr. H. Alex Choi (Professor of Neurosurgery and Neurology at UT Health Houston McGovern Medical School, member of the Grace Scientific Advisory Board.) highlighted the trial results demonstrating the safety and tolerability of GTx-104 in the treatment of aSAH.

“Results from the STRIVE-ON trial showed that intravenous GTx-104 has the potential to deliver its potent neuroprotective effects while reducing hypotensive events compared to orally administered nimodipine. Additionally, subjects treated with GTx-104 had improvements in ICU length of stay and reduction in the need for mechanical ventilation,” said Dr. Choi. “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.”

“The presentation of our STRIVE-ON data at the*Neurocritical Care Society* annual meeting caps a very eventful and productive period for Grace, led by the FDA’s acceptance for review of our New Drug Application (NDA) for GTx-104,” said Prashant Kohli, CEO of Grace Therapeutics. “The presented data reinforce the potential of GTx-104 as a major innovation in the treatment of aSAH patients. These data were well received by the clinicians and pharmacists attending the conference, who expressed their excitement about the potential of I.V. administered GTx-104 to better manage hypotension and dose compliance. The standard of care for aSAH has not seen meaningful innovation in nearly 40 years, and we believe our STRIVE-ON trial results point to a very promising role for GTx-104 in the treatment of these patients, if approved. We look forward to continuing to engage with the FDA during their review as they work toward their PDUFA target date of April 23, 2026.”

The STRIVE-ON safety 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 secondary endpoints included safety, clinical, and pharmacoeconomic outcomes.

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 aSAH, a relatively uncommon type of stroke 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 I.V. 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 I.V. infusion.

GTx-104 provides a convenient I.V. 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 200 patients and 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) 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 I.V. 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: 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 and the outcome of the FDA's review of the Company's NDA submission for GTx-104, benefits of GTx-104's Orphan Drug Designation, 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 medical and pharmacoeconomic benefit, GTx-104's commercial prospects, and the Company's patent estate and its ability to extend exclusivity of GTx-104, 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 of the Company's NDA for GTx-104; (iii) changes to regulatory pathways; (iv) the Company's ability to maintain effective patent rights and other intellectual property protection for its product candidates and (v) legislative, regulatory, political and economic developments. 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, 2025, the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2025 filed with the Securities and Exchange Commission (SEC) and other documents that have been and will be filed by Grace Therapeutics from time to time with the SEC 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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