August 27, 2025

Grace Therapeutics Announces U.S. Food and Drug Administration Acceptance for Review of New Drug Application for GTx-104

FDA Establishes April 23, 2026 as PDUFA Target Date for Review of Submission Seeking Approval for GTx-104 in the Treatment of Patients with aneurysmal Subarachnoid Hemorrhage (aSAH)

Comprehensive Data Package Supported by Positive Results from Phase 3 STRIVE-ON Safety Trial of GTx-104

PRINCETON, N.J., Aug. 27, 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 IV infusion to address significant unmet medical needs in aSAH patients, today announced that on August 22, 2025 the U.S. Food and Drug Administration (FDA) accepted the Company's New Drug Application (NDA) for GTx-104 for formal review. The application seeks approval for GTx-104 for the treatment of patients with aSAH, and is supported by a comprehensive data package including positive data obtained from the Company's Phase 3 STRIVE-ON safety trial of GTx-104. The FDA established a Prescription Drug User Fee Act (PDUFA) target date of April 23, 2026 for its review of the Company's NDA submission.

"FDA acceptance for review of our NDA for GTx-104 for the treatment of aSAH is another significant milestone for Grace Therapeutics, further demonstrating our ability to execute as we continue to advance this important innovation for aSAH patients," said Prashant Kohli, Chief Executive Officer of Grace Therapeutics. "Our NDA is supported by a robust data package including positive results from our STRIVE-ON trial, which provide support for improved clinical outcomes in aSAH patients and both medical and pharmacoeconomic evidence of the potential benefit of GTx-104 in the treatment of aSAH. 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, if approved, as a potential breakthrough for the care of aSAH patients. We look forward to engaging with the FDA during their review process."

Acceptance of the NDA for review triggers the potential exercise of up to $7.6 million in warrants issued as part of a private placement the Company completed in September 2023. Under the terms of the September 2023 private placement, each warrant is exercisable for one share of common stock at an exercise price of $3.003 per share. These warrants are currently exercisable and will expire on the earlier of (i) the 60th day after the date of the acceptance by the FDA of an NDA for the Company's product candidate GTX-104 or (ii)

September 25, 2028.

Grace has obtained Orphan Drug Designation from the FDA for GTx-104, which generally provides seven years of marketing exclusivity in United States upon FDA approval of the NDA. Additionally, the Company believes that its U.S. and international patent estate will protect the market value of GTx-104 beyond marketing exclusivity.

About the STRIVE-ON Safety Trial

The STRIVE-ON safety trial (NCT05995405) 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. 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% patients receiving GTx-104 had relative dose intensity (RDI) of 95% or higher compared to only 8% on oral nimodipine, and 29% more patients receiving GTx-104 had favorable functional outcomes at 90 days compared to oral nimodipine. In addition, there were 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.

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 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 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 IV 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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