October 30, 2024

Grace Therapeutics to Host Virtual KOL Event on GTx-104 in aneurysmal Subarachnoid Hemorrhage on November 20, 2024

PRINCETON, N.J., Oct. 30, 2024 (GLOBE NEWSWIRE) -- Grace Therapeutics, Inc. (Nasdaq: GRCE) (Grace Therapeutics or the Company), a late-stage, biopharma company advancing GTx-104, its novel injectable formulation of nimodipine that addresses high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced it will host a virtual key opinion leader (KOL) event on Wednesday, November 20, 2024 at 2:00 PM ET. To register, click here.

The event will feature Abhishek Ray, MD (University Hospitals) and Andrew Webb, PharmD, BCCCP (Massachusetts General Hospital), who will discuss the high unmet medical need and current treatment landscape for patients suffering from aneurysmal Subarachnoid Hemorrhage (aSAH), a rare and life-threatening medical emergency.

A live question and answer session will follow the formal presentations.

About Abhishek Ray, MD

Abhishek Ray, MD, is a fellowship-trained, board-certified neurological surgeon at University Hospitals and Associate Professor of neurological surgery at Case Western Reserve University School of Medicine. He specializes in caring for people with cerebrovascular disease (brain aneurysms, stroke, AVMs), pituitary tumors and meningiomas, and in minimally invasive techniques to treat degenerative spine disease.

In neurological surgery, there are often multiple ways to treat a single problem, and Dr. Ray is committed to providing each patient with an individualized care plan to optimize results. In 2021, 2022, 2023, and 2024, he was selected by his peers to be included in Cleveland Magazine's list of Top Doctors.

After completing his undergraduate degree in biological systems engineering at the University of California – Davis, Dr. Ray went back to his hometown to attend medical school at the University of Kansas School of Medicine in Kansas City, Kansas, where he was elected to be an ambassador of the school and was inducted into the Alpha Omega Alpha Honor Medical Society. He then went on to complete neurological surgery residency at University Hospitals/Case Western Reserve University School of Medicine, where he also completed fellowship training in neuro-interventional surgery.

Dr. Ray stayed on as faculty at UH/Case Western Reserve University School of Medicine to advance neurosurgical education there. He created a unique and comprehensive neurological surgery elective for second-year medical students, of which he is now the

course director. He has been an instructor at national skull base courses for neurosurgical residents and fellows and has served as editor of the neuro-interventional section of CNS Nexus, an online library of neurosurgical cases to better prepare trainees for the operating room.

About Andrew Webb, PharmD, BCCCP

Andrew Webb, PharmD, BCCCP, is a board-certified neurocritical care clinical pharmacy specialist at Massachusetts General Hospital (MGH) and serves as adjunct clinical faculty at Northeastern University School of Pharmacy and Pharmaceutical Sciences. His clinical and research interests include subarachnoid hemorrhage, status epilepticus, traumatic brain injury, and optimizing the medical management of neurocritically ill patients and his clinical practice is on the multidisciplinary neurocritical care team at MGH's 22-bed neurosciences intensive care unit.

Dr. Webb is originally from Rhode Island and completed his undergraduate studies and Doctor of Pharmacy at the University of Rhode Island. He then completed his pharmacy practice residency at Mayo Clinic in Rochester, MN followed by residency in critical care at Oregon Health & Science University in Portland, OR.

Dr. Webb serves on the MGH Comprehensive Stroke Center Quality Taskforce and the MGH Neurology Quality Assurance and Committee on Patient Safety, focusing on improving the quality, safety, and effectiveness of medication therapy in stroke, subarachnoid hemorrhage, and other neurologic conditions. He is active in the Neurocritical Care Society, American College of Clinical Pharmacy, and Society for Critical Care Medicine and serves on several committees within these organizations related to critical care and neurology practice, research, and education. He has lectured regionally and nationally on the pharmacotherapy of subarachnoid hemorrhage, status epilepticus, and the unique challenges of pharmacotherapy in neurocritical care.

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. Outside of the United States, annual cases of aSAH are estimated at approximately 60,000 in the European Union, and approximately 150,000 in China.

About the Grace Therapeutics Asset Portfolio

GTx-104 is a clinical stage, novel, injectable formulation of nimodipine being developed for intravenous (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. The addressable market in the United States for GTx-104 is estimated to be about $300 million, based on market research.

GTx-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve neurological symptoms of Ataxia-Telangiectasia (A-T), for which there are currently no FDA-approved therapies. GTX-102 is a stable, concentrated oral spray formulation comprised of the gluco-corticosteroid betamethasone that, together with other excipients can be sprayed conveniently over the tongue of the A-T patient and is rapidly absorbed. The further development of GTx-102 has been deprioritized in favor of our focus on development of GTx-104. It is also possible that we may license or sell our GTx-102 drug candidate.

GTx-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to ease the symptoms of patients suffering with postherpetic neuralgia (PHN). GTx-101 is administered via a metered-dose of bupivacaine spray and forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. It also comes in convenient, portable 30 ml plastic bottles. Unlike oral gabapentin and lidocaine patches, we believe that the biphasic delivery mechanism of GTx-101 has the potential for rapid onset of action and continuous pain relief for up to eight hours. No skin sensitivity was reported in a Phase 1 trial. The further development of GTx-101 has been deprioritized in favor of our focus on development of GTx-104. It is also possible that we may license or sell our GTx-101 drug candidate.

About Grace Therapeutics

Grace Therapeutics is a late-stage biopharma company with drug candidates addressing rare and orphan diseases. Grace Therapeutics'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. Grace Therapeutics'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'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: 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 timing of a data readout from the Company's Phase 3 STRIVE-ON safety trial of GTx-104, the timing of the Company's planned NDA submission with the FDA in connection with the Company's Phase 3 STRIVE-ON safety trial, GTx-104's commercial prospects; the size of the addressable market for GTx-104, the Company's beliefs regarding the potential benefits of GTx-104, including GTx-104's potential to bring enhanced treatment options to patients suffering from aSAH, and the anticipated benefits and future development, license or sale of the Company's other drug candidates are based upon Grace Therapeutics'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 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'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 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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