Gate Neurosciences Emerges from Stealth with a Portfolio of Next-Generation Therapies for Central Nervous System Diseases

- Established by an experienced neuroscience team with a track-record of successful drug development, including former founders of Naurex
- Assembled a clinical-stage CNS portfolio and using precision medicine approaches to develop treatments for neuropsychiatric and cognitive disorders
- Focused on next-generation mechanisms that target synaptic dysfunction and restore healthy brain signaling by enhancing neuroplasticity, representing some of the most potent and well-tolerated approaches known to-date
- Lead molecule, Zelquistinel, is a 3rd generation NMDAR modulator acquired from AbbVie

CARMEL, Ind., August 23, 2022 — *Gate Neurosciences today announced it has officially launched to develop its next-generation therapeutics addressing synaptic dysfunction in patients suffering from central nervous system (CNS) disorders.*

Gate was founded in 2019 by a team of neuroscience industry veterans to address the increasingly urgent need for more effective treatments for CNS disorders, and to overcome long-standing challenges in CNS drug development. Since its founding, the company has acquired a robust portfolio of next-generation compounds from large pharma, along with corresponding data from thousands of patients dosed across numerous clinical trials that will inform and de-risk future development.

“We formed Gate to bring forward precision medicine approaches to CNS disorders, such as biomarkers and enrichment for responders, similar to the early days of targeted oncology drug development” remarked Anantha Shekhar, co-founder of Gate Neurosciences and Senior Vice Chancellor for Health Sciences and Dean of the University of Pittsburgh School of Medicine. “Gate’s lead programs are supported by a uniquely robust package of clinical and translational data across thousands of patients, and we’re excited to continue advancing the molecules using deep precision insights.”

The company is focused on developing novel mechanisms that address synaptic dysfunction underlying neuropsychiatric and cognitive disorders, including major depressive disorder (MDD). Gate’s lead programs stem from a platform of novel NMDA receptor modulators that have demonstrated rapid, durable, and safe outcomes across multiple published and unpublished clinical studies. The company’s unique mechanism represents a more direct and well-tolerated approach to enhancing synaptic function and neuroplasticity, compared to ketamine and other next-generation rapid antidepressants.

“Current therapies for mental health disorders are extremely inadequate and patients need better options. There has never been more evidence that enhancing underlying synaptic function is the ideal therapeutic approach” commented Mike McCully, Chief Executive Officer at Gate. “We believe our novel synaptic modulators are the most potent and proven compounds

that enhance synaptic function to achieve rapid, durable, and safe outcomes with potential across a wide range of neuropsychiatric disorders."

Gate's lead program, Zelquistinel, is an oral 3rd generation NMDAR modulator that was discovered by Naurex and advanced into the clinic by Allergan before its acquisition by AbbVie. To date, Zelquistinel has completed multiple Phase 1 EEG biomarker studies and an initial Phase 2a dose exploration study in MDD. Gate also acquired global rights to the 2nd generation NMDAR modulator Apimostinel, which the company is developing for acute psychiatric indications based on a large 24-hour effect size observed in a Phase 2a proof-of-concept study. These programs are supported by a deep de-risking translational data package, including over 500 patients dosed with Apimostinel and Zelquistinel across multiple clinical studies, to inform future development of the molecules.

The company's development plans for Zelquistinel and Apimostinel also leverage key learnings from the first-generation NMDAR molecule, Rapastinel (Glyx-13), which demonstrated proof-of-concept across multiple clinical MDD studies in combined over 2,000 patients. Gate is collaborating with psychiatry leaders to continue exploring Rapastinel in investigator-led clinical studies, given its established safety profile and the company's more advanced understanding of Rapastinel's dose dynamics.

Gate will provide a strategic business update in the coming weeks that will provide additional information on its diverse development portfolio and major recent and upcoming milestones. Further details on the company's portfolio may be found on Gate's website, gateneuro.com

About Gate Neurosciences
Gate Neurosciences is a precision medicine biotechnology company focused on advancing next-generation CNS treatments that address growing needs in mental health. The company is developing a portfolio of novel mechanisms of action that enhance synaptic function to address neuropsychiatric and neurocognitive diseases, including major depressive disorder (MDD). Using learnings from extensive clinical, preclinical, and translational data and a better understanding of CNS development challenges, the company is advancing its clinical pipeline using evidence-driven, precision psychiatry approaches.

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