

Gate Neurosciences Hones in on Precision Medicine with Expanded Research Operations Supporting Its Synaptic Function-Enhancing Molecules

- *Expanded research operations led by Drs. Joseph Moskal and Jeffery Burgdorf of Northwestern University, pioneers of the “stinel” class of NMDA receptor modulators*
- *Research focused on advancing translational qEEG biomarkers, dosing, and mechanism insights underlying Gate’s synaptic function enhancing molecules*
- *Key insights further support a next confirmatory Phase 2 study of lead oral program zelquistinel in major depressive disorder*

INDIANAPOLIS, May 3, 2023 — Gate Neurosciences, a clinical-stage biotechnology company using precision medicine approaches to develop next-generation neuroscience therapies, today announced it has increased its R&D capabilities with new expanded research operations and lab facilities in Evanston, Illinois.

There, Gate will further build the translational biomarker data package supporting its NMDA receptor modulator portfolio and advance foundational mechanism insights behind its synaptic function-enhancing molecules. The expanded research supports parallel clinical development of the “stinel” class including lead oral program zelquistinel in Phase 2 for major depressive disorder (MDD).

Expanded Translational Biomarker and Synaptic Function Research

Gate Neuro has expanded its R&D operations with new lab facilities located in Evanston, IL including nearly 2,000 sq. ft. of lab space, cutting-edge CNS research and biomarker tools, plus a vivarium. Gate is increasing its research capabilities to focus on refining translational biomarkers of synaptic function that could help bring precision medicine to mood disorders through better understanding of dosing dynamics and patient enrichment in clinical trials. Initial data from this research will be presented at the upcoming American Society of Clinical Psychopharmacology (ASCP) annual meeting in May 2023.

The multi-pronged research effort will continue building upon decades of ‘stinel development as novel rapid-acting antidepressants and enhancers of synaptic function. The research team will be led by Dr. Jeff Burgdorf PhD, a leader in mood disorder and NMDAR pharmacology and advised by Dr. Joseph Moskal PhD, 30+ pioneer of Gate’s NMDAR modulator class, and Dr. John Donello PhD, biopharma executive who led translational development of Gate’s lead program, zelquistinel, through biomarker and Phase 2a studies.

“Over the past 30 years, we have pioneered the science behind a new class of pharmacology that enhances synaptic function through NMDA receptor modulation,” said Dr. Moskal. “We believe the ‘stinel class has transformative potential to impact psychiatric disease. Our renewed

research offers an exciting opportunity to further unlock the foundational science behind these molecules, and position them for near-term clinical success and long-term impact on patients.”

Focus on Dosing Insights

A key focus of Gate’s expanded research is continuing to validate the company’s dose model behind its NMDAR modulators that underlies successful clinical outcomes observed across the class, through biomarkers of target engagement and long-term potentiation – a key measure of synaptic function. Translational insights from this work will be analyzed in tandem with results from a previously announced Phase I multiple-ascending dose and EEG biomarker trial of apimostinel. Gate expects to gain a more nuanced understanding of how dose levels and intervals can be optimized for enduring effects on synaptic function in patients, which further optimizes a next Phase 2 study with its lead oral program, zelquistinel. Topline readout from the apimostinel biomarker study is expected mid-2023.

“Since we acquired these compounds from AbbVie, Gate’s focus has been on continuing to build and validate the data package and dose model underlying this class of NMDAR molecules,” commented Mike McCully, CEO of Gate Neurosciences. “Single doses of the ‘stinels have long-lasting effects on synaptic function, which means it is critical to understand repeat dosing dynamics to optimize the pharmacodynamic effect. Our expanded research efforts will continue validating our dose model and building confidence in the next Phase 2 study of zelquistinel in MDD.”

About Gate Neurosciences

Gate Neurosciences, headquartered in Indianapolis, is a precision medicine biotechnology company focused on advancing next-generation central nervous system (CNS) treatments that address the 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. Using learnings from extensive clinical, preclinical and translational data, along with a better understanding of CNS development challenges, the company is advancing its clinical pipeline using evidence-driven, precision psychiatry approaches.

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