Gate Neurosciences Announces Clinical Collaboration with Beacon Biosignals to Advance Precision EEG Biomarkers in Major Depressive Disorder

Collaboration entails the use of Beacon Biosignals' FDA-cleared Dreem™ 3S device in an upcoming Phase 2 clinical trial of Gate's lead oral program, zelquistinel, in Major Depressive Disorder

INDIANAPOLIS, January 24, 2024 – Gate Neurosciences, a clinical-stage biotechnology company using precision medicine approaches to develop next-generation neuroscience therapies, today announced a strategic collaboration with Beacon Biosignals to further advance the use of electroencephalogram (EEG) biomarkers across the company's clinical pipeline in neuropsychiatry and cognition.

Initially, this collaboration will entail the use of Beacon Biosignals' FDA-cleared Dreem™ 3S headband device and neurobiomarker platform to conduct exploratory EEG and sleep analyses in depressed patients enrolled in Gate's upcoming Phase 2 trial of zelquistinel, slated to initiate by mid-2024. Zelquistinel is a rapid-acting, once-weekly oral NMDA receptor positive modulator in development for treating major depressive disorder (MDD).

"The Gate team is excited to partner with Beacon in pioneering a new era of precision psychiatry with innovative biomarker insights, approaches, and technology" commented Mike McCully, CEO of Gate Neurosciences. "We will apply data and key learnings obtained from our combined experience in psychiatric clinical studies and EEG analyses to ultimately improve outcomes for patients across mental health, cognitive, and neurodevelopmental disorders."

The collaboration represents the next phase of precision psychiatry for Gate, building on its existing biomarker research including EEG data from prior zelquistinel clinical studies and translational EEG insights at the company's recently expanded R&D operations in Evanston, Illinois. In November of 2023, the company announced positive results from a Phase 1 EEG biomarker study of apimostinel (second-generation injectable NMDA receptor modulator), which demonstrated a consistent, dose-dependent human EEG signature representing NMDAR target activation. In the upcoming zelquistinel Phase 2 depression study, Gate will use Beacon's biomarker platform for deeper insights into patient diagnoses, treatment response, and target activation over six weeks of dosing.

"In psychiatry, outcomes can vary widely within the same diagnosis; making it difficult for patients, families, and providers to determine the best treatment pathway for any individual," said Jacob Donoghue, M.D., Ph.D., CEO of Beacon Biosignals. "Brain activity during sleep, as measured using Beacon's at-home hardware and AI-powered software, will provide a level of precision understanding never before possible, empowering informed and accurate decisions for the treatment of conditions such as depression. We look forward to working with the team at

Gate on the upcoming clinical trial for zelquistinel, and to making further progress on this cutting-edge research."

Beacon Biosignals' analytics platform combines its large clinical EEG databases and proprietary machine-learning algorithms to identify neurobiomarkers that assist with patient stratification, assessing drug activity and therapeutic efficacy. A key component of this platform is the Dreem™ 3S EEG device, which is U.S. Food and Drug Administration cleared and clinically validated. The wearable device measures sleep architecture and EEG activity in patients with central nervous system disorders and is optimized for comfortable, longitudinal brain monitoring. The Dreem™ 3S data flows into Beacon Biosignals' analytics platform to provide validated neurophysiological endpoints for clinical trials.

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.

About Beacon Biosignals
Beacon's machine learning platform for EEG enables and accelerates new treatments that transform the lives of patients with neurological, psychiatric or sleep disorders. Through novel machine learning algorithms, large datasets, and advances in software engineering, Beacon Biosignals is changing the way patients are treated for disorders of the brain. For more information, visit https://beacon.bio/. For careers, visit https://beacon.bio/careers; for partnership inquiries, visit https://beacon.bio/contact. Follow us on Twitter (@Biosignals) or LinkedIn (https://www.linkedin.com/company/beacon-biosignals).

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