THE
ERP Biomarker
QUALIFICATION CONSORTIUM

Industry Consortium Launched to Qualify Biomarkers for Schizophrenia Drug Development

Group Aims to Bring Disease-Associated Biomarker Through FDA's Drug Development Tools Qualification Program

Louisville, KY., March 20, 2019 – The ERP Biomarker Qualification Consortium was launched today by pharmaceutical industry members with the goal of qualifying event-related potential (ERP) biomarkers to aid the development of new investigational therapies for people with schizophrenia in accordance with FDA guidelines[1]. The Consortium, which brings together industry, academic and regulatory stakeholders, also aims to standardize ERP measurements so they are consistent across treatment centers and can be used to stratify patient populations and evaluate the effects of new treatments.

Principal industry members of the Consortium include Alkermes, Inc. (ALKS), Anavex Life Sciences Corp. (AVXL), Cadent Therapeutics, H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY), Merck (known as MSD outside the United States and Canada) (MRK), Neuronetrix Solutions, LLC (dba Cognision), Sage Therapeutics, Inc., and Takeda Pharmaceutical Company Limited (TAK).

Central nervous system (CNS) disease experts Daniel C. Javitt, M.D., Glytech, Inc.; David P. Walling, Ph.D., CNS Network, LLC; Larry Ereshefsky, PharmD, Follow the Molecule, LLC; and Richard Keefe, Ph.D., VeraSci, will serve as advisory members.

"The discovery and development of novel treatments for schizophrenia has been challenging in part due to the lack of qualified biomarkers to quantify the heterogeneity and pathophysiology of the underlying disease," said Tim Piser, Ph.D., Chief Scientific Officer of Cadent Therapeutics. "By establishing qualified ERP biomarkers, our goal is to standardize measurements based on disease biology, which will be a welcomed complement to current observational and behavioral assessments. This will enable us to better stratify patients and measure their progress when taking a novel therapy."

"In the past, ERP testing was limited due to equipment complexity and variability, which often led to inconsistent results," said KC Fadem, Chief Technology Officer and Founder of Neuronetrix Solutions, LLC (dba Cognision). "Today, with the availability of low-cost, easy-to-use, automated equipment, like the COGNISION® System, ERP testing techniques could be optimized to support schizophrenia clinical trials. We are proud to be part of the ERP Biomarker

[1] FDA Drug Development Tools Qualification Program

Qualification Consortium and look forward to helping bring new and effective therapies to patients with schizophrenia."

The ERP Biomarker Qualification Consortium will run clinical studies to support qualification of the ERP biomarker. The studies are designed to evaluate ERP levels in patients with schizophrenia and healthy adults. Key objectives are to determine baseline measures and evaluate how these measures change in response to pharmaceutical interventions.

About ERPs

Event-related potentials (ERPs) are changes in the electroencephalogram (EEG) caused by sensory and cognitive processes. In schizophrenia, ERP deficits are associated with cortical synaptic pathophysiology, such as NMDAr (N-methyl-D-aspartate receptor) hypofunction, which is related to cognitive impairment experienced by these patients. For example, mismatch negativity (MMN) is an ERP associated with auditory novelty detection. MMN is impaired and correlates with cognitive and global function in patients with schizophrenia. The ability to measure a biomarker like MMN may play a predictive role in schizophrenia drug development.

About the ERP Biomarker Qualification Consortium, LLC

The ERP Biomarker Qualification Consortium, LLC, a subsidiary of Neuronetrix Solutions, LLC (dba Cognision), is a pharmaceutical industry collaboration that was established to formally qualify normative event-related potential (ERP) biomarkers with the goal of advancing and streamlining the clinical development of new investigational therapies for people with schizophrenia. Founding principal members include Alkermes, Inc., Anavex Life Sciences Corp., Cadent Therapeutics, H. Lundbeck A/S, Merck (known as MSD outside the United States and Canada), Neuronetrix Solutions, LLC (dba Cognision), Sage Therapeutics, Inc., and Takeda Pharmaceutical Company Limited.

For more information, please visit https://erpbiomarkers.org

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