



At AES 2018 Cognizance Biomarkers Unveils Data Showing It Can Accurately Distinguish between Epileptic and Psychogenic Nonepileptic Seizures

*—Evogen/Cognizance Biomarkers' Blood-Based Biomarker Test Has Potential to Transform Costly, Time-Consuming and Imprecise Diagnosis of Epilepsy—
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Spring House, PA, and New Orleans, LA, December 3, 2018 – Cognizance Biomarkers, LLC, a wholly-owned subsidiary of Evogen, Inc., a leader in proteomic and genomic-based testing for improved diagnosis and treatment of neurological disorders, today reported that a [study](#)¹ being presented at the 2018 Annual Meeting of the American Epilepsy Society (AES) shows its blood-based neuroinflammatory biomarker test and algorithm can accurately distinguish epileptic seizures (ES) from psychogenic nonepileptic seizures (PNES).

Psychogenic nonepileptic events are common--accounting for an estimated 20% or more of patients seeking medical care at comprehensive epilepsy centers. They resemble and are hard to distinguish from true epileptic seizures and are related to psychological factors rather than electrical disturbances in the brain. Since epilepsy is difficult to diagnose, individuals with psychogenic nonepileptic seizures are often assumed to have epilepsy and receive unnecessary testing and treatment, including powerful antiepileptic drugs. They also risk losing driver licenses and other privileges. One study found that wrongly diagnosed psychogenic patients received unnecessary antiepileptic therapy for an average of seven to 10 years.²

Peter Crino, MD, PhD, is Chair of the Department of Neurology at the University of Maryland School of Medicine and a co-author of the new study. His former laboratory at the University of Pennsylvania conducted key studies of Cognizance Biomarkers' approach. Dr. Crino noted, "Many individuals are being treated for epilepsy who do not actually have this disorder. Individuals with psychogenic nonepileptic seizures are especially at risk for an epilepsy misdiagnosis. These results provide strong preliminary evidence that neuroinflammatory-associated biomarkers can be used to triage suspected seizure patients for expert evaluation, thereby ensuring that patients are accurately diagnosed and appropriately treated."

Epilepsy is currently diagnosed using electroencephalograms (EEGs) and comprehensive patient assessments. The process can be subjective, cumbersome, expensive and inconclusive. Video EEGs are more informative, but they require costly hospitalization. Cognizance Biomarkers' simple-to-administer blood test aims to accurately diagnose epileptic seizures based on proprietary methods for biomarker assessment, leveraging recent research showing that neuroinflammation is associated with epilepsy and is both a cause and consequence of seizures. Prior clinical studies have confirmed the ability of the Cognizance neuroinflammatory biomarker test to distinguish actual seizures from seizure-like events.

In the study reported today, researchers screened for levels of 51 inflammatory-associated proteins in post-event blood samples from confirmed epilepsy patients and individuals with psychogenic nonepileptic seizures. A series of analyses selected four protein biomarkers that were highly predictive in distinguishing true seizures from seizure-like events. Additional analyses identified substantial differences in clinical histories and comorbidities (i.e. risk factors) between ES and PNES patients. The selected neuroinflammatory-associated biomarkers were combined with the PNES risk factors to generate and refine a diagnostic algorithm that demonstrated strong performance in distinguishing true epileptic seizures from nonepileptic psychogenic seizures with 100% specificity, 87% sensitivity and 98% accuracy.

Todd Wallach, President and Chief Executive Officer of Evogen/Cognizance Biomarkers, commented, "These new data further confirm that our biomarker-based blood test has the potential to revolutionize the diagnosis of epilepsy. The results we are presenting today address one of the most vexing diagnostic issues in epilepsy—differentiating true epileptic seizures from similar-seeming psychogenic nonepileptic events. Our neuroinflammatory biomarker test combined with selected psychogenic risk factors accurately distinguished these two groups. Our blood-based diagnostic test will enable epilepsy to be diagnosed and treated more rapidly and accurately and has the potential to guide epilepsy clinical research and manage treatment over the lifecycle of the condition."

This research was conducted with grant support from the National Institutes of Health.

The [2018 AES Annual Meeting](#) is being held in New Orleans, LA from Nov. 29-Dec.4, 2018.

1 – Poster Session 3, Dec. 3, 2018; 8:00am-2:00pm.

[AES Poster 3.094](#) - Predictive Blood Test for Psychogenic Nonepileptic Seizures: Post hoc Assessment of Plasma Biomarkers and Risk Factors, JM Gledhill, Jr., E Brand, R St. Clair, T Wallach, J Pollard, PB Crino

2- Benbadis, S. "The differential diagnosis of epilepsy: a critical review." *Epilepsy & Behavior* 15.1 (2009): 15-21

About Epilepsy

Epilepsy is a chronic neurological disorder affecting approximately 65 million people worldwide and more than 2 million people in the U.S., where it is the fourth most common neurological disorder. Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age. There are many different types of epilepsy, but the main characteristic of the condition is recurrent seizures. The accurate diagnosis of epilepsy remains a challenge, as current methods are subjective, cumbersome, expensive and imprecise.

About Evogen/Cognizance Biomarkers

Evogen, Inc. is a leading developer of diagnostic, detection and sample collection solutions with successful products deployed worldwide. Cognizance Biomarkers LLC, a wholly owned subsidiary of Evogen, is a clinical stage neurology and neuroinflammation-focused diagnostics company focused on achieving leadership in proteomic and genomic-based testing for improved diagnosis and treatment of neurological disorders, offering rapid, accurate and cost-effective precision medicine solutions for optimal patient outcomes. Cognizance Biomarkers' patented EvoScoreDX™ biomarker-based blood test has the potential to help revolutionize the diagnosis of epilepsy. In clinical studies, EvoScoreDX demonstrated sensitivity and specificity of 90% or more. The company is also developing EvoScoreGX™ comprehensive genomic testing for improved management of neurological disorders. For more information, visit evogen.com.

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