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BISCAYNE NEUROTHERAPEUTICS REPORTS SUCCESSFUL PHASE 1b CLINICAL TRIAL RESULTS FOR ITS NOVEL ANTIEPILEPTIC AGENT

— Extended Release BIS-001ER Met All Pre-Defined Endpoints Including Twice-Daily Dosing, Good Tolerability and Blood Levels Surpassing Those Needed to Suppress Seizures—

—Proof of Concept Efficacy Study in Adults with Refractory Focal Seizures Slated for Early 2018—

Miami, FL– October 19, 2017 – Biscayne Neurotherapeutics, Inc., a clinical-stage company developing novel agents for the treatment of neurological disorders, today announced results from a Phase 1b trial of its novel antiepileptic compound, BIS-001*ER*. In the trial, the new extended release version of BIS-001 met or surpassed all pre-defined endpoints, including dosing frequency, serum drug exposure and safety. Biscayne intends to initiate a BIS-001*ER* proof of concept efficacy study in adults with refractory focal seizures in early 2018. The company will discuss the Phase 1b results at the 8th Annual Sofinnova Japan Biopharma Partnering Conference in Tokyo, Japan on October 24.

Stephen Collins, MD, PhD, President and Chief Executive Officer of Biscayne Neurotherapeutics, said, "These results exceeded our expectations and are consistent with the encouraging safety profile seen in numerous studies of BIS-001 in animals, as well as its record of safe use for hundreds of years as a traditional Chinese medicine. This successful Phase 1b study sets the stage for the proof of concept efficacy trial in adults with refractory focal epilepsy we will initiate early next year. Biscayne will also soon be launching a Series C financing that will enable us to pursue an accelerated clinical program for BIS-001*ER* in Dravet syndrome and other hard-to-treat epilepsies."

In the Phase 1b study in healthy volunteers, BIS-001*ER* achieved its goal of twice-daily dosing, a regimen preferred by many epilepsy physicians and patients. On average, serum drug exposure levels were almost twice as high as the levels researchers think are needed to achieve strong efficacy results (based on dosages in animal models that suppressed 100% of seizures in at least half the subjects.) Adverse events were as expected and were generally mild to moderate, transient and non-dose limiting.

BIS-001 is a highly potent form of huperzine A, a synthetic extract of a traditional Chinese medicine with a long history of safe use. Huperzine A is an acetylcholinesterase (AChE) inhibitor with high brain penetration that offers a unique mechanism of action for the treatment of epilepsy. It has shown promising efficacy in highly predictive preclinical models of refractory epilepsy, providing complete elimination of seizures in the majority of animals. Biscayne's extended release formulation of BIS-001 is designed to enhance tolerability across a range of doses and ensure patient convenience and medication adherence. Biscayne is developing BIS-001*ER* to treat refractory forms of focal epilepsy, including Focal Impaired Awareness Seizures (previously known as Complex Partial Seizures.) It has been awarded a U.S. FDA Orphan Drug designation for BIS-001 for the treatment of Dravet syndrome, a devastating seizure condition affecting children.

Steven Schachter MD, Professor of Neurology at Harvard Medical School and a Scientific Co-Founder of Biscayne, commented, "These positive findings support proceeding to clinical efficacy assessments of BIS-001*ER*, which has exhibited excellent anti-seizure activity preclinically. In addition, huperzine A has demonstrated cognition enhancement in people with dementing conditions, so we are hopeful it may be beneficial for epilepsy patients with cognitive dysfunction. At a minimum, we are optimistic BIS-001*ER* will not have the detrimental effects on cognition seen with many existing antiepileptic drugs. This would be an important advance in these conditions with high unmet need for more effective therapies with fewer adverse effects."

Epilepsy is a chronic disorder characterized by recurrent, unprovoked seizures. Epilepsy affects about three million people in the US and over 50 million people worldwide. In more than half of patients, the

cause is unknown. Many patients with epilepsy have more than one type of seizure and may also have other symptoms of neurological problems. Up to one in 3 patients with epilepsy is unable to control their seizures with current therapies whether taken alone or in combination.

About Biscayne Neurotherapeutics

Biscayne Neurotherapeutics is a clinical-stage biotechnology company developing novel drugs for serious central nervous system disorders such as refractory epilepsy. Biscayne's lead compound BIS-001*ER* has shown striking efficacy in highly predictive models of difficult-to-treat epileptic conditions, such as focal seizures and Dravet syndrome. Biscayne is headquartered in Miami, FL. For more information, visit biscayneneurotherapeutics.com.

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