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**BISCAYNE NEUROTHERAPEUTICS LICENSES CHINESE RIGHTS TO ITS NOVEL ANTIEPILEPTIC AGENT TO GLOBAL DRUG DEVELOPMENT CENTRE (GDCC) CHINA**

*—Biscayne Will Provide GDCC Expert Assistance to Speed Development and Marketing of BIS-001ER in China—*

*—Separately, Biscayne Announces Start of Phase 2 Trial in Most Common Type of Adult Epilepsy—*

**Miami, FL– March 28, 2018** – Biscayne Neurotherapeutics, Inc., a clinical-stage company developing novel agents for the treatment of neurological disorders, today announced a licensing agreement with Global Drug Development Centre (GDCC) China, registered as China Global Bio-Pharmaceutical Industry Development (Chengdu) Co., Ltd., for rights to Biscayne’s lead antiepileptic product BIS-001ER in China, Taiwan, Hong Kong and Macau. The agreement gives GDCC rights to BIS-001ER’s intellectual property in these territories and provides for Biscayne to provide technical assistance to GDCC to facilitate the development, regulatory approval and marketing of the product. Biscayne Neurotherapeutics received an upfront payment from GDCC and is also eligible to receive milestone payments and royalties on BIS-001ER sales. Financial details were not disclosed.

Separately, Biscayne announced initiation of a Phase 2 study of BIS-001ER in subjects with Focal (onset) Impaired Awareness Seizures (FIAS), the most common form of adult epilepsy. BIS-001ER is a novel agent that has shown promising results in preclinical models of severe epilepsy and successfully completed a Phase 1b safety trial late last year.

Stephen Collins, MD, PhD, President and Chief Executive Officer of Biscayne Neurotherapeutics, said, “We are delighted to finalize an agreement for the development and marketing of BIS-001ER in China, the world’s largest market for antiepileptics. The agreement is an example of the multiple benefits we are realizing from our relationship with Quark Ventures and the Global Health Sciences Fund, which led our 2017 Series B financing. They were instrumental in facilitating this partnership with GDCC, their drug development and marketing affiliate in China.”

Dr. Collins continued, “Notably, BIS-001ER is a highly potent form of huperzine A, a synthetic extract of a traditional Chinese medicine with a long history of safe use in neurological disorders. We look forward to the opportunity to provide technical assistance to our colleagues at GDCC as they develop and market this promising new agent with the potential to help the many epilepsy patients poorly served by current treatments.”

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. Biscayne’s extended release formulation is designed to enhance tolerability across a range of doses and ensure patient convenience and medication adherence. In a Phase 1b study, BIS-001ER achieved its goal of twice-daily dosing and exhibited serum drug exposure levels that were almost twice as high as the levels researchers think are needed to achieve strong efficacy results. Adverse events were generally mild to moderate, transient and non-dose limiting.

Jesson Chen, Chairman of Global Drug Development Centre (GDCC) China, commented, “Its promising efficacy and safety profile and roots in traditional Chinese medicine make BIS-001ER a potentially valuable new therapy for the Chinese epilepsy market. Our researchers are eager to initiate a clinical program in China, and we expect that Biscayne will provide us with valuable assistance as we move to advance our development activities for BIS-001ER.”

The Phase 2 proof of concept trial will assess the ability of BIS-001*ER* to reduce seizures in subjects with the most common form of adult epilepsy, Focal Impaired Awareness Seizures (FIAS), previously known as Complex Partial Seizures. FIAS affects an estimated 35% of adults with epilepsy. FIAS seizures that are not responsive to treatment cause serious, life-altering problems for patients and can be fatal. While some patients achieve good control with current treatments, there is substantial unmet need for more therapeutic options. The Phase 2 study is being conducted at two internationally-recognized epilepsy centers of excellence in Australia using a well-validated robust design that includes advanced video EEG techniques. Results are expected later this year.

Biscayne is developing BIS-001*ER* to treat refractory forms of focal epilepsy, including FIAS and catastrophic pediatric onset epilepsies such as Dravet and Lennox Gastaut syndromes. It has been awarded a U.S. FDA Orphan Drug designation for the treatment of Dravet syndrome.

Epilepsy is a chronic disorder characterized by recurrent, unprovoked seizures. Epilepsy affects about three million people in the U.S. 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 [biscayneurotherapeutics.com](http://biscayneurotherapeutics.com).

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