

Contacts:

Biscayne Neurotherapeutics
Corporate:
Jared Mendel
(786) 502-4220
info@biscayneuro.com

Media:
BLL Partners
Barbara Lindheim
(212) 584-2276
blindheim@bllbiopartners.com

BISCAYNE ANNOUNCES FORMATION OF BISCAYNE NEUROTHERAPEUTICS AND COMPLETION OF SERIES B FINANCING

—Financing Enables New Spin-out of Biscayne Pharmaceuticals to Advance Novel Antiepileptic Agent BIS-001 into Phase 1b Clinical Trial in 2017—

—In Recently Published Study, BIS-001 Completely Eliminated Seizures in Most Animals in a Model of Severe Epilepsy—

Miami, FL– January 27, 2017 – Biscayne Neurotherapeutics, Inc., a clinical-stage company established by Biscayne Pharmaceuticals to develop its biopharmaceutical assets for the treatment of neurological disorders, today announced completion of a \$3 million Series B financing. The financing was led by the Global Health Sciences Fund of Quark Venture and GF Securities, along with Mesa Verde Venture Partners. Existing Biscayne Pharmaceuticals investors and new private investors also participated. Biscayne Neurotherapeutics will primarily use the funds to conduct a Phase 1b trial of a new extended release form of its novel antiepileptic compound, BIS-001, in development for adults with refractory complex partial seizures.

Stephen Collins, MD, PhD, President and Chief Executive Officer of Biscayne Neurotherapeutics, commented, “Patients with severe epilepsies urgently need more effective therapies with fewer disabling side effects. BIS-001 has demonstrated exceptional anti-seizure activity preclinically and an encouraging safety profile in a Phase 1a trial. We are delighted that our new and existing investors have provided the financing to advance our new extended release formulation of BIS-001 into a Phase 1b clinical trial that is scheduled to begin by mid-year. If all goes well, we expect to initiate a Phase 2a trial in 2018 and to pursue an accelerated clinical program in a number of hard-to-treat epilepsies.”

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 the animals. In a Phase 1a trial in patients with drug-resistant epilepsy, BIS-001 appeared safe and well tolerated at dosages planned for future studies. Biscayne has now developed an extended release formulation of BIS-001, which is designed to enhance tolerability across a range of doses and ensure patient convenience and medication adherence. Biscayne is initially developing BIS-001 to treat refractory forms of focal epilepsy, including refractory partial complex seizures and Dravet syndrome, a devastating refractory condition afflicting children.

“The goal of the Global Health Sciences Fund is to invest in the best science the world has to offer, so we are pleased to partner with Biscayne Neurotherapeutics, whose innovative science has emerged from researchers at Harvard and Yale,” said Karimah Es Sabar, Chief Executive Officer, Quark Venture. “We are impressed with the company’s leadership and their unique approach to finding a solution for these devastating diseases, for which there are currently no adequate therapies available.”

“We are committed to building partnerships with promising life sciences companies addressing important unmet needs,” said Carey Ng, PhD, MBA, Managing Director of Mesa Verde Venture Partners. “Biscayne’s team has deep epilepsy expertise and a lead compound with a novel mechanism of action, a long history of safe use and impressive preclinical data in a well-validated model of severe epilepsy. We welcome this opportunity to support the company as it advances the clinical program for BIS-001.”

Steven Schachter MD, Professor of Neurology at Harvard Medical School and a Scientific Co-Founder of Biscayne, commented, “In addition to its powerful anti-seizure activity in preclinical models of severe epilepsy, BIS-001 has exhibited the cognition-enhancing properties seen with other AChE drugs, but with much better central nervous system and systemic tolerability and safety than currently available agents.

Our clinical program will assess both anti-seizure efficacy and whether BIS-001 supports improved cognition in epilepsy patients. At a minimum, we are optimistic it will be devoid of the detrimental effects on cognition seen with many existing antiepileptic drugs. We are eager to test BIS-001 in a variety of conditions, given the high unmet therapeutic need that exists across the spectrum of seizure disorders.”

As part of the financing agreement, the Global Health Sciences Fund will appoint one director and one observer to the Biscayne Neurotherapeutics Board of Directors, and Mesa Verde Venture Partners will also name a director.

Samuel Reich, a Co-Founder and Executive Chairman of Biscayne Neurotherapeutics, noted, “We welcome the involvement and investment of Quark Venture and GF Securities, as well as Mesa Verde Venture Partners and the company’s other new and existing investors. Our new venture investors bring us diverse biopharmaceutical industry expertise, along with new funding to progress our highly promising lead therapy for people with severely disabling epilepsy. We also appreciate the fact that they have the depth of resources needed to support our future efforts as BIS-001 advances in clinical trials.”

Epilepsy is a chronic disorder, the hallmark of which is 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 1 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 has shown striking efficacy in highly predictive models of difficult-to-treat epileptic conditions such as complex partial seizures and Dravet syndrome. Biscayne’s technology is licensed from Harvard University, Yale University and the University of South Florida. Biscayne is headquartered in Miami, FL. For more information, visit the company’s website, biscayneneurotherapeutics.com, which is currently under construction but should be operative shortly.

About Quark Venture

Quark Venture Inc. is focused on equity financing of innovative biotechnology and health sciences companies with breakthrough technology platforms and projects. In late 2016, Quark Venture and GF Securities Company Limited, a leading investment bank in China, announced a new US\$500 million Global Health Sciences Venture Fund that invests globally in a diversified portfolio of innovative biotechnology and health sciences companies who are addressing unmet medical needs through innovations in drug development, medical devices, health IT and emerging convergent technologies. For more information on Quark Venture visit www.quarkventure.com.

About GF Securities

Incorporated in September of 1991, GF Securities is a provider of comprehensive capital market services with industry-leading innovation capabilities focused on serving China’s quality SMEs and affluent individuals. GF Securities is listed both on the Hong Kong (01776.HK) and Shenzhen (000776.SZ) stock exchanges with total market capitalization of approximately US\$20 billion. GF Securities is an industry leader across the entire spectrum of its core business services: investment banking, wealth management, trading and institutional client services, and investment management. For more information, visit www.gf.com.cn.

About Mesa Verde Venture Partners

Mesa Verde Venture Partners is an early-stage life sciences venture capital firm focused on creating partnerships with entrepreneurs to build successful companies. Mesa Verde Venture Partners was founded in 2006 and is based in San Diego, CA. The firm’s charter is to invest in a diversified portfolio of early-stage biotechnology and medical technology companies with a focus in the Southwest and other traditionally underrepresented areas in biomedical venture capital. Areas of interest include therapeutics, medical devices, diagnostics, life science tools, and healthcare wireless/IT. For more information, visit mesaverdevp.com.

###