

Contacts:

Biscayne Pharmaceuticals
Corporate:
Jared Mendel
(786) 502-4220
info@biscaynepharma.com

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

BISCAYNE PHARMACEUTICALS MERGES WITH INSERO HEALTH, ADDING CLINICAL-STAGE NOVEL EPILEPSY PROGRAM AND OTHER CNS ASSETS

—Insero Scientific Co-founder and Harvard Epilepsy Expert Dr. Steven Schachter Joins Biscayne as Senior Science Advisor—

—Drug Development Veteran Stephen Collins Is Named CEO and Launches Series B Financing—

Miami Beach, FL– October 5, 2015 – Biscayne Pharmaceuticals, Inc., a biopharmaceutical company developing novel therapies for cancer and other conditions based on growth hormone-releasing hormone (GHRH) analogs, today announced that it has merged with Insero Health, a developer of novel treatments for epilepsy, pain and other central nervous system (CNS) disorders. Stephen Collins, MD, PhD, formerly Chief Executive Officer of Insero Health, has become President and CEO of Biscayne Pharmaceuticals. Samuel Reich, who co-founded both Biscayne and Insero Health, will retain the position of Executive Chairman of the combined companies. Financial details of the transaction were not disclosed.

Insero's lead compound, BIS-001, is a highly potent and selective acetylcholinesterase inhibitor (AChE) that is a synthetic form of a single agent traditional Chinese medicine. It has demonstrated striking efficacy in highly predictive models of difficult-to-treat epilepsies, such as Dravet syndrome and refractory Complex Partial (Focal) Seizures. In Insero's Phase 1 study in adults with drug-resistant complex partial epilepsy, BIS-001 was safe and well-tolerated, and blood levels necessary for development of an extended release form of the drug were established.

Epilepsy affects about three million people in the U.S. and over 50 million people worldwide. Many patients with epilepsy take multiple medications, yet the published literature suggests that as many as one-third are unable to control their seizures with current therapies.

Biscayne is continuing development of new cancer therapies based on a novel molecular target--growth hormone-releasing hormone (GHRH) receptors. GHRH normally acts on receptors in the pituitary to produce the growth hormone needed for tissue growth and repair. Biscayne's Scientific Co-Founder, Dr. Andrew V. Schally, discovered that cancer cells also have GHRH receptors and produce GHRH on their own. Biscayne is developing GHRH antagonists that inhibit tumor growth by blocking the activity of tumoral GHRH. In xenograft studies, these antagonists have shown excellent safety and promising anti-tumor activity in a range of cancers, and the company believes they may have therapeutic potential in multiple types of difficult-to-treat tumors.

"Biscayne now is in the enviable position of having two novel platforms with excellent proprietary protection championed by world class scientists and targeting refractory conditions with major unmet needs," said Mr. Reich. "Insero was co-founded by Harvard neurology professor Dr. Steven Schachter, a leading epilepsy expert who has conducted more than 70 epilepsy clinical trials over the course of a highly distinguished career, and Biscayne's cancer program is based on the work of Nobel laureate Dr. Andrew Schally, a renowned endocrine researcher and prolific drug developer. Our new CEO, Dr. Stephen Collins, brings Biscayne extensive successful drug development and management experience at both global pharmaceutical and entrepreneurial biotechnology companies."

Mr. Reich continued, "With a Phase 1b/2a proof-of-concept epilepsy trial planned for 2016, our lead cancer compound entering initial IND-enabling studies and an expanded, highly experienced management team in place, we believe we are well-positioned to launch the series B financing that will enable us to advance these high potential programs."

Dr. Collins noted, "The impetus for my joining Insero was my enthusiasm for the potential of our innovative approach to provide a safe and effective treatment option for the large population of epilepsy patients who remain poorly controlled on current therapies. I am delighted to bring this novel program, which may additionally have applications in pain and other CNS conditions, to Biscayne, where we also

are developing first-in-class cancer agents based on a promising new molecular target in a biomarker-driven program that is focusing on refractory cancers with high unmet need.”

Dr. Collins has extensive experience in the development of new drugs. Before joining Insero, he was CEO of NeuroTherapeutics Pharma, and Chief Scientific Officer & Vice President, Clinical Affairs at Ovation Pharmaceuticals, where he oversaw R&D, won FDA approval for the orphan drugs vigabatrin and clobazam, and advanced multiple programs in oncology and neuroscience into late stage development. Prior to Ovation, Dr. Collins was Global Senior Director of CNS and Pain at Johnson & Johnson, overseeing early-stage development of CNS agents. At Abbott Laboratories, Dr. Collins contributed to the FDA approval of such drugs as Depakote ER[®] and Depacon[®]. He earned an AB degree in Biophysics at the University of California, Berkeley and MD and PhD degrees at Case Western Reserve University.

About Biscayne Pharmaceuticals

Biscayne Pharmaceuticals is a clinical-stage biotechnology company developing drugs for difficult-to-treat conditions in two major disease areas: CNS disorders such as refractory epilepsy and drug-resistant cancer. Both programs are based on novel approaches with demonstrated potential for superior efficacy and safety. Lead CNS 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. A Phase 1b/2a study is planned for 2016. Biscayne is also developing new cancer therapies that block growth hormone-releasing hormone (GHRH) receptors, a novel target that is present on many cancer cells. Biscayne plans to initiate IND-enabling studies for lead cancer agent BIS-1062 in the coming months. Biscayne’s technology is licensed from Harvard University, the University of Miami, Yale University and the University of South Florida. Biscayne is headquartered in Miami, FL. For more information, visit biscaynepharmaceuticals.com