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BISCAYNE PHARMACEUTICALS PRESENTS DATA ON NOVEL ANTIEPILEPTIC AGENT BIS-001 AT EILAT CONFERENCE ON NEW ANTIEPILEPTIC DRUGS

Madrid, Spain and Miami Beach, FL USA– June 28, 2016 – Biscayne Pharmaceuticals, Inc., today reported that it presented data on lead compound BIS-001 at the Thirteenth Eilat Conference on New Antiepileptic Drugs in Madrid, Spain. BIS-001 is a clinical-stage, highly potent and selective acetylcholinesterase (AChE) inhibitor that is a synthetic form of the traditional Chinese medicine huperzine A. Biscayne is initially developing BIS-001 for the treatment of adults with complex partial seizures (CPS) and children with the devastating condition Dravet syndrome. About 30% of CPS patients are fully refractory to current therapy and there are no approved treatments for Dravet syndrome.

Data presented by Biscayne President and CEO Stephen Collins, MD, PhD, showed that in studies sponsored by the U.S. National Institutes of Health (NIH), BIS-001 exhibited striking preclinical efficacy in predictive epilepsy models. It showed high central nervous system (CNS) penetration, with a very high affinity for the antiepileptic site of action and low systemic effects. In contrast to other agents in the class tested by the NIH that were only effective at toxic doses, BIS-001 demonstrated superior efficacy to existing products at doses that appeared well-tolerated. BIS-001 is also far more potent than marketed antiepileptic drugs--it was 57 times more potent than the standard of care therapy levetiracetam (Keppra®) and completely eliminated seizures in a mouse model of Dravet's.

Dr. Collins also presented pharmacokinetic data from a Phase 1a study of the original oral immediate release formulation of BIS-001. The data showed that the immediate release formulation would have required frequent dosing and that it produced high peak serum levels associated with non-serious, but annoying side effects. Biscayne is currently developing novel extended release formulations of BIS-001 with improved pharmacokinetic profiles that will reduce dosing frequency. Dr. Collins discussed preliminary data on the prototype extended release formulations, which exhibit improved pharmacokinetics with gradual, controlled release rates that support twice-daily dosing regimens. Further studies of the new formulations are underway, and the company expects to initiate a Phase 1b trial with one of the new formulations in 2016.

Dr. Collins commented, "Epilepsy is a disabling disorder that affects millions of Americans, yet remains poorly treated. BIS-001, which is a synthetic form of the widely used natural product huperzine A, may have the potential to provide an effective and safe treatment option for refractory disease. Its long history of safe use in a variety of CNS applications also substantially minimizes the risk that we will encounter new safety or tolerability issues during development. In addition, huperzine A has shown promise as a cognition enhancer in the treatment of dementia, so BIS-001 may have the potential to positively impact the mental functioning of epilepsy patients, whose cognition can be adversely affected by current drugs. We are pleased with the progress we have made in developing an improved extended release formulation of BIS-001 and hope to advance it into a Phase 1b clinical trial later this year."

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

The Thirteenth Eilat Conference on New Antiepileptic Drugs is being held June 26-29, 2016.

About Biscayne Pharmaceuticals
Biscayne Pharmaceuticals is a clinical-stage biotechnology company developing drugs 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. 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'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