



## **The NIH Awards Sun BioPharma, Inc. Grant to Study SBP-101 for the Treatment of Pancreatitis**

### **Company Reports Improved Drug Manufacturing Process**

**Minneapolis, MN, February 1, 2017-** Sun BioPharma, Inc., (OTCQB: SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today announced the Company has been awarded a Small Business Technology Transfer (STTR) grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), one of the National Institutes of Health, to study the effect of their flagship product, SBP-101, as a potential treatment for pancreatitis. SBP-101 is a first-in-class, proprietary, polyamine compound designed to exert therapeutic effects in a mechanism specific to the pancreas.

The studies funded by the grant will be performed in collaboration with researchers at Cedars-Sinai Medical Center in Los Angeles, CA under the direction of the Chief of the Department of Gastroenterology, Dr. Stephen Pandol. Dr. Pandol, a former President of the American Pancreatic Association, is a world-renowned researcher and clinician who has published extensively on pancreatitis, pancreatic cancer and diabetes. Dr. Michael Walker, recipient of the grant and Director of Pancreatic Research at Sun BioPharma, will lead the effort, working with researchers in The Pandol Laboratory, which is dedicated to establishing and maintaining leading international research at Cedars-Sinai for the prevention, early diagnosis and treatment of pancreatic diseases.

“We are excited to be able to study SBP-101 in pancreatitis with such a highly respected research team,” said Dr. Walker. “Pancreatitis represents a significant unmet medical need with very limited treatment options.” Dr. Pandol added, “Treatment for pancreatitis consists mainly of pain management and supportive care. Development of a direct treatment would represent a

major advance in the management of this disease, and we are pleased to work with Sun BioPharma to further elucidate the effects of SBP-101 on the basic pathophysiology of pancreatitis.”

Pancreatitis, or inflammation of the pancreas, is responsible for approximately 300,000 in-patient hospital admissions annually in the United States and is the leading reason for hospitalization of patients with gastrointestinal diseases. It is estimated that over \$2 billion per year is spent on the direct medical costs of treating these patients.

Patients with pancreatitis experience abdominal pain, which can be severe and/or life threatening. The disease occurs most often in adults aged 30-40 years and is usually associated with the consumption of alcohol and tobacco or with the presence of stones in the gallbladder. In some cases the cause is unknown. Patients with pancreatitis are at higher risk for developing both diabetes and pancreatic cancer.

Current treatment is limited to supportive care with intravenous fluids and pain management. There is no direct treatment to the pancreas itself. The funding provided by NIDDK will enable the Company to further understand the basic physiology of pancreatitis and evaluate the potential for SBP-101 to be used to specifically treat pancreatitis. SBP-101 is currently in clinical development for the treatment of patients with refractory metastatic pancreatic cancer.

In addition, as part of its commitment to continuous quality assurance, Sun BioPharma recently completed certain improvements to the manufacturing process of SBP-101, and submitted details of its progress to the FDA. Drug product created using the new manufacturing process will be incorporated into the Company’s ongoing Phase 1 cancer study through a protocol amendment that adds an additional 3 patients, to be dosed with the new drug product, in the currently enrolling 5<sup>th</sup> patient cohort. With timely institutional review board and ethics committee approvals, the Company expects that all patients in that cohort will complete dosing by the end of the first quarter of 2017. The Company further notes that it believes that it now has produced enough drug product to complete the clinical proof of concept for SBP-101.

The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

## **About SBP-101**

SBP-101 is a first-in-class, proprietary, polyamine compound designed to exert therapeutic effects in a mechanism specific to the pancreas. Sun BioPharma originally licensed SBP-101 from the University of Florida in 2011. The molecule has been shown to be highly effective in preclinical human pancreatic cancer models, demonstrating superior activity to existing FDA-approved chemotherapy agents. Combination therapy potential has also been shown for pancreatic cancer. SBP-101 is expected to differ from current pancreatic cancer therapies in that it specifically targets the exocrine pancreas and has shown efficacy against primary and metastatic disease in animal models of human pancreatic cancer. Therefore management believes that SBP-101 may effectively treat both primary and metastatic pancreatic cancer, while leaving the insulin-producing islet cells and non-pancreatic tissue unharmed.

## **About Sun BioPharma**

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for urgent unmet medical needs. The Company's development programs target diseases of the pancreas, including pancreatitis and pancreatic cancer; the Company's initial product candidate is SBP-101 for the treatment of patients with pancreatic cancer. SBP-101 was invented by Raymond Bergeron, Ph.D., a Distinguished Professor Emeritus at the University of Florida. Sun BioPharma has scientific collaborations with pancreatic disease experts at Cedars Sinai Medical Center in Los Angeles, the University of Miami, the University of Florida, the Mayo Clinic Scottsdale, the Austin Health Cancer Trials Centre in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, Australia. Further information can be found at: [www.sunbiopharma.com](http://www.sunbiopharma.com). Sun BioPharma's common stock is currently quoted on the OTCQB tier of the over-the-counter markets administered by the OTC Markets Group, Inc. under the symbol: SNBP.

## **About Cedars-Sinai**

Cedars-Sinai is a leader in providing high-quality healthcare encompassing primary care, specialized medicine and research. Since 1902, Cedars-Sinai has evolved to meet the needs of one of the most diverse regions in the nation, setting standards in quality and innovative patient care, research, teaching and community service. Today, Cedars-Sinai is known for its national leadership in transforming healthcare for the benefit of patients. Cedars-Sinai impacts the future of healthcare by developing new approaches to treatment and educating tomorrow's health professionals. Additionally, Cedars-Sinai demonstrates a commitment to the community through programs that improve the health of its most vulnerable residents. For more information, visit [www.cedars-sinai.edu](http://www.cedars-sinai.edu).

## **Safe Harbor**

*Statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Sun BioPharma, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products,*

*uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, maintenance of intellectual property rights and ability to satisfy ongoing requirements for quotation on the OTCQB. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of Sun BioPharma particularly those mentioned in the cautionary statements found in Sun BioPharma's filings with the Securities and Exchange Commission. Sun BioPharma disclaims any intent or obligation to update these forward-looking statements.*

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