



**Compelling Preclinical Data on Sun BioPharma's SBP-101 Presented at the 2015  
American Pancreatic Association (APA) Annual Meeting**

**Minneapolis, MN, November 9, 2015** - Sun BioPharma, Inc. (OTCPink: SNBP), a biopharmaceutical company currently focused on developing therapies for pancreatic cancer, announced today that three presentations detailing preclinical data on its lead development candidate, SBP-101, were delivered at the 2015 American Pancreatic Association (APA) annual meeting held in San Diego, CA.

SBP-101 is an analogue of a polyamine naturally occurring in mammalian cells. The polyamine transport uptake mechanism is reported to be up-regulated or accelerated in various tumor types, including pancreatic ductal adenocarcinoma (PDA). Inducing polyamine depletion via the cellular uptake of a synthetic polyamine analogue has been proposed as an anti-tumor strategy. Based upon results achieved in preclinical testing, Sun BioPharma believes that SBP-101 may be a promising treatment for PDA and has been awarded Orphan Drug Status by the United States Food and Drug Administration (FDA). SBP-101 has been granted Investigational New Drug (IND) status by the FDA and the Company has opened a Phase 1 clinical study of SBP-101 in Australia and expects to begin clinical study in the United States during the first quarter of 2016.

Suzanne Gagnon, MD Chief Medical Officer of Sun BioPharma presented the results of a study evaluating the anti-proliferative effect of SBP-101 in the presence and absence of gemcitabine (GEM) and/or nab-paclitaxel (NAB) in six human PDA cell lines. SBP-101 alone produced an anti-proliferative effect in all six cell lines with maximal inhibition generally occurring at 96 hours and at the 10  $\mu$ M dose level (where >80% inhibition of cell viability in four of the six cell lines was demonstrated). SBP-101 alone was more effective than GEM + NAB, the current standard

of care, in most cell lines. However, the combination of SBP-101 with GEM and NAB exhibited the greatest inhibitory effect.

Ajit Shah, PhD, Vice President, Clinical Pharmacology of Sun BioPharma presented the results of a study evaluating the efficacy of SBP-101 alone and in combination with GEM and/or NAB in a mouse xenograft model. Fragments of the human pancreatic cell line, BxPC-3, were implanted subcutaneously in mice and allowed to grow before treatment with SBP-101 or with a combination of SBP-101 and GEM and/or NAB. Tumor growth inhibition (defined as the percent difference between median tumor volumes of treated and control mice) was 64% and 78% for two different dose schedules of SBP-101 alone and exceeded 92% when SBP-101 was administered in combination with GEM and/or NAB. Efficacy was supported by partial and/or complete tumor regression responses in all treatment combinations.

Archana Sareen, PhD from the University of Minnesota, presented the results of the University's research evaluating the mechanism of action of SBP-101 on pancreatic acinar and ductal cells which demonstrated the induction of caspase 3 mediated apoptosis.

"This pre-clinical data confirms the anti-neoplastic potential of SBP-101 and offers a compelling rationale for its clinical development as a potentially promising treatment for human pancreatic cancer", commented David Kaysen, President and Chief Executive Officer of Sun BioPharma. "The presentations generated significant interest in SBP-101 and expectations for the results of the Sun BioPharma's Phase 1 clinical trial that is expected to begin in Australia by year end 2015 and to begin in the US in the first quarter of 2016."

### **About SBP-101**

SBP-101 is a first-in-class proprietary polyamine compound designed to exert its therapeutic effect in a mechanism specific to the pancreas. SBP-101 specifically targets the exocrine pancreas and represents a promising agent for the treatment of both primary and metastatic pancreatic cancer, while leaving the insulin-producing islet cells and non-pancreatic tissue unaffected. Sun BioPharma licensed SBP-101 from the University of Florida in 2011. Prior studies presented at the American Association for Cancer Research (AACR) and PancreasFest examined the anti-neoplastic effects of subcutaneous administration of SBP-101 following orthotopic implantation of human L3.6pl pancreatic cancer cells into the pancreas of mice. SBP-

101 inhibited the growth of pancreatic cancer cells, prolonged survival in mice, and demonstrated an enhanced effect when co-administered with gemcitabine, a current cornerstone of pancreatic cancer chemotherapy.

The company believes that SBP-101 represents a novel approach that has the potential to effectively treat both pancreatic cancer and pancreatitis. In the last 20 years only four treatment regimens for pancreatic cancer have been approved by the FDA and no drugs have been approved for the specific treatment of patients with pancreatitis. Pancreatic cancer is expected to be the second leading cause of cancer deaths in the US by 2020, surpassed only by lung cancer. Pancreatic ductal adenocarcinoma (the target cancer in the SBP-101 Phase I clinical trial) represents approximately 95% of all pancreatic cancers and has a 5-year survival rate of approximately 7%.

### **About Sun BioPharma**

With offices in Gainesville, FL and Waconia, MN, Sun BioPharma Inc. is a next-generation biopharmaceutical company developing disruptive therapeutics for significant unmet medical needs. The company's initial programs are aimed at diseases of the pancreas, including pancreatic cancer and pancreatitis. Sun BioPharma has clinical collaborations with pancreatic disease experts at The Ohio State University, the Fred Hutchinson Cancer Center in Seattle, Translational Genomics (TGen) in Scottsdale, AZ, the Austin Health Olivia Newton John Cancer & Wellness Centre and the Box Hill Monash University Hospital in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, Australia. Further information can be found at: [www.sunbiopharma.com](http://www.sunbiopharma.com).

### **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, and maintenance of intellectual property rights. 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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