



## **Sun BioPharma to Initiate Fifth Patient Cohort in its Dose Escalation Phase 1 Study of SBP-101 for Pancreatic Cancer**

- *Data Safety Monitoring Board (DSMB) for the Study Unconditionally Approves Moving into Fifth Cohort*
- *Through Four Cohorts 15 Patients Have Received Escalating Doses of SBP-101*

MINNEAPOLIS, MN, December 7, 2016 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: SNBP), a biopharmaceutical company developing disruptive therapeutics for the treatment of patients with pancreatic diseases, today announced that the Data Safety Monitoring Board (DSMB), an independent group of medical experts closely monitoring the Company’s clinical study, has completed its safety review of the data from cycle 1 dosing of the fourth cohort of patients. As a result of this review by the DSMB, Sun BioPharma has begun recruiting patients for the fifth patient cohort in the dose escalation phase of the study. The Company currently expects to begin dosing patients in the fifth cohort as early as December 12, 2016, which is approximately 60 days after the fourth patient cohort commenced dosing.

“Our safety data from this Phase 1 Study continue to be encouraging,” said Suzanne Gagnon, M.D., Sun BioPharma’s Chief Medical Officer. “Once again there were no dose-limiting toxicities in the fourth group and no drug-related serious adverse events occurred. Patients are tolerating SBP-101 very well! We continued to see no evidence of bone marrow toxicity. Based on the unconditional approval by the DSMB we will immediately commence with the recruitment of the fifth cohort of patients using a higher dose of SBP-101.”

“We are encouraged by the enthusiasm for our Phase 1 trial at the study sites as we continued the rapid pace of enrollment with our fourth cohort allowing us to move quickly into the fifth cohort. Through our first four cohorts, we have dosed and captured data

from 15 patients, some of whom have completed multiple dosing cycles. This represents a significant base of safety data for SBP-101,” commented David B. Kaysen, President and CEO of Sun BioPharma. “We are extremely grateful for the dedication of the clinical teams at our study sites and for the patients who have volunteered to be part of our study.”

Two of the Company’s study sites are in the United States: Mayo Clinic Scottsdale and HonorHealth, both in Scottsdale, AZ and three study sites are in Australia: The Ashford Cancer Centre in Adelaide, the Olivia Newton-John Cancer & Wellness Centre and Box Hill Hospital at Monash University, both in Melbourne.

### **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 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 the Phase 1 Safety Study of SBP-101 in Patients with Previously Treated Pancreatic Cancer**

Sun BioPharma is currently conducting a clinical trial of SBP-101 in patients with previously treated locally advanced or metastatic pancreatic cancer. This is a Phase 1, first-in-human study with a dose-escalation phase and an expansion phase at the anticipated recommended treatment dose. This study is being conducted at clinical sites in both the United States and Australia including Mayo Clinic Scottsdale and HonorHealth in Scottsdale, AZ, the Austin Health Cancer Trials Centre and the Box Hill Hospital in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, Australia.

### **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 pancreatic cancer and pancreatitis; the Company’s initial product candidate is SBP-101 for the treatment of patients with pancreatic cancer. SBP-101 was invented by Ray Bergeron, Ph.D. Distinguished Professor Emeritus, 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 and the Box Hill 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). 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.

### **Forward-Looking Statements 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" For purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements that are not historical fact (including, but not limited to statements that contain words such as "will", "believes," "may," "anticipates," "expects," "estimates" or "plans") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, our need to obtain additional capital to support our business plan, which may not be available on acceptable terms or at all, risks inherent in the development and/or commercialization of potential products, uncertainty in the pace of enrollment and results of clinical trials or regulatory approvals 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 Sun BioPharma and its business, particularly those disclosed from time to time in Sun BioPharma's filings with the Securities and Exchange Commission. Shareholders and other readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they are made. Sun BioPharma disclaims any intent or obligation to update these forward-looking statements.*

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