



## **SUN BIOPHARMA, INC. DOSES FIRST PATIENTS IN SECOND CLINICAL STUDY OF SBP-101 FOR PANCREATIC DUCTAL ADENOCARCINOMA**

- After Successful Completion of the Phase 1 Dose Escalation/Safety Study of SBP-101, New Combination Study Opens for Previously Untreated Metastatic Pancreatic Cancer Patients
- SBP-101 is a Proprietary Polyamine Analogue Targeted Specifically for Pancreatic Diseases
- SBP-101 was Invented by Emeritus Professor Raymond Bergeron at the University of Florida in Gainesville, Florida, USA with World-Wide Exclusive Rights Licensed to Sun BioPharma, Inc.

**MINNEAPOLIS, MN and MELBOURNE, AUSTRALIA**, June 13, 2018 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB:SNBP) and its wholly owned subsidiary, Sun BioPharma Australia Pty Ltd, a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with pancreatic diseases, announced today that on June 4, 2018 the first patients were enrolled in a Phase 1a/1b study of SBP-101 in combination with gemcitabine and nab-paclitaxel for front-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDA). Sun BioPharma Australia Pty Ltd, is the sponsor of this study. The Phase 1a portion of this study will treat up to 18 PDA patients in three cohorts in order to determine a recommended dose of SBP-101 to be given in combination with standard treatment. The Phase 1b portion will be an expansion at the recommended dose of SBP-101, and will guide SBP-101's subsequent development for patients with PDA. This multi-center, front-line study has 3 sites in Australia, The Austin Health Cancer Trials Centre in Melbourne, The Adelaide Cancer Centre in Adelaide, The Blacktown Cancer and Haematology Centre in Sydney and one site in the United States, The University of Florida Health Cancer Center in Gainesville, Florida. The first patients have been enrolled at the Adelaide Cancer Centre in Adelaide, Australia under the direction of Associate Professor Dusan Kotasek and at the University of Florida Health Cancer Center in Gainesville, Florida under the direction of Thomas J. George, MD, F.A.C.P.

Dr. Kotasek received his medical degree at the University of Adelaide and specialty training in Haematology and Oncology at The Queen Elizabeth Hospital followed by a Fellowship at the University of Minnesota, in Minneapolis, MN, USA. A Co-Founder of the Adelaide Cancer Centre, Dr. Kotasek has published over 60 scientific papers in oncology, and he is one of Australia's leading cancer clinical research experts. Dr. Kotasek, the Principal Investigator for this study at the Adelaide Cancer Centre commented, "Pancreatic cancer is a challenging disease with few

significant options available with a meaningful impact on response rates and progression free survival. We are excited to participate in this clinical study, and to continue our evaluation of SBP-101 as front-line combination treatment for previously untreated patients with metastatic PDA.”

Dr. George is a medical oncologist having graduated with honors from the University of Florida College of Medicine. He is the Director of the GI Oncology Program at the University of Florida and Associate Director of Clinical Investigation at the UF Health Cancer Center. He is the Principal Investigator for this study at the University of Florida Health Cancer Center and he commented, “We are extremely honored to be participating in this important study that was born from the discoveries made by Dr. Raymond Bergeron here at the University of Florida. Pancreatic cancer requires us to think outside the box which is exactly what this treatment has the potential to offer our patients with PDA.”

“Pancreatic cancer is a leading cause of cancer deaths in both Australia and the United States, currently being the 3<sup>rd</sup> most common cause of cancer deaths in the US. It represents a significant unmet medical need, with most patients having a poor prognosis and limited life expectancy,” said Suzanne Gagnon, M.D., Chief Medical Officer at Sun BioPharma. “Our recently completed safety study in heavily pre-treated PDA patients suggested SBP-101 could be a promising addition to current front-line treatment regimens. The Data Safety Monitoring Board, Principal Investigators and our clinical team agreed to move directly to front-line for our second trial and we are excited to study SBP-101 in combination with standard of care chemotherapy for previously untreated metastatic PDA patients.”

### **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 Research Foundation in 2011. The molecule has been shown to be highly effective in preclinical studies of 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. The safety and metabolic profile demonstrated in our first-in-human safety study further supports evaluation of the potential for additive or synergistic effects in combination with current standard pancreatic cancer treatment.

### **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 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, the Ashford Cancer Centre in Adelaide, Australia and The Blacktown Cancer and Haematology Centre in Sydney, Australia. The Company's independent Data Safety Monitoring Board (DSMB) is Chaired by James Abbruzzese, MD, Professor of Medicine, Charles Johnson, M.D. Professor of Medicine, a member of the Duke Cancer Institute and Chief, Division of Medical Oncology at Duke University School of Medicine. Professor David Goldstein, FRACP, Senior Staff Specialist at the Prince Henry & Prince of Wales Hospital / Cancer Care Centre in Sydney, Australia is Co-Chair of the DSMB. 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**

*This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. For example, statements regarding the Company's next study, the timing and effects of the reverse stock split and potential eligibility and approval for listing on a national securities exchange are forward-looking statements. Any other 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 are not a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by such forward-looking statements, including, without limitation, the anticipated timing of first patient enrollment, our need to obtain additional capital, 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 results or timing of clinical trials or regulatory approvals, timing of necessary regulatory processes relating to the reverse stock split, and other material changes in our business that could jeopardize our ability to qualify for listing on a national securities exchange. 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 Company and its business, particularly those disclosed from time to time in its filings with the Securities and Exchange Commission. Stockholders 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. The Company disclaims any intent or obligation to update these forward-looking statements.*

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