



Sun BioPharma Receives DSMB Approval to Start Fourth Patient Cohort in the Dose Escalation Phase 1 Study of SBP-101 for Pancreatic Cancer

MINNEAPOLIS, MN, (GLOBE NEWSWIRE)—October 6, 2016 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 clinical trial, has completed its safety review of the data from the dosing of the third cohort of patients. As a result of this positive review by the DSMB, Sun BioPharma has initiated the fourth patient cohort in the dose escalation phase of the study. The Company currently expects to begin dosing patients in the fourth cohort as early as October 10, 2016, which is approximately 60 days after the third 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 third group and no drug-related serious adverse events occurred. In addition, we have not observed any evidence of bone marrow toxicity. Based on the review by the DSMB we will commence with the enrollment of the next cohort of patients using a higher dose of SBP-101.”

The Data Safety Monitoring Board is chaired by James Abbruzzese, MD, Professor of Medicine, member of Duke Cancer Institute and Chief, Division of Medical Oncology at Duke University School of Medicine, who is one of the foremost leaders in the clinical study and treatment of pancreatic cancer and co-chaired by Dr. David Goldstein, Conjoint Professor and a Senior Staff Specialist in the Department of Medical Oncology at Prince of Wales Hospital in Sydney, Australia who has extensively studied the influence of host cells on tumor progression in pancreatic cancer.

“We are encouraged by the enthusiasm for the Phase 1 trial at our study sites as evidenced by the rapid enrollment in the third cohort and the identification and screening of potential patients for the fourth cohort,” commented David B. Kaysen, President and CEO of Sun BioPharma. “The combination of this rapid enrollment with the acceleration of the DSMB review is accelerating the pace of the study which may now complete by Q2 2017, which is significantly earlier than we had anticipated when the trial started.”

Three of the Company’s 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 and two study sites are in the United States: the Mayo Clinic Scottsdale and Honor Health, both in Scottsdale, AZ.

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 Australia and the United States 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. 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.

Contact Information:

EVC Group

Investor Contact:

Doug Sherk
415-652-9100
Michael Polyviou
212-850-6020

Media Contact:

Dave Schemelia
646-201-5431