



Sun BioPharma, Inc. Announces Completion of the Fifth Patient Cohort in the Dose Escalation Phase 1a Study of SBP-101 for Pancreatic Cancer

- *Next Cohort of Patients Initiates Pathway to Determining Maximum Tolerated Dose (MTD)*
- *Summary Data of First Five Cohorts Show Efficacy Signals*

MINNEAPOLIS, MN, JUNE 5, 2017 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB:SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today announced completion of the fifth patient cohort in the dose-escalation phase of the Company's Phase 1 clinical study using SBP-101 to treat patients with locally advanced or metastatic pancreatic ductal adenocarcinoma (PDA).

Phase 1a Trial Update

After review of the fifth cohort patients by the Data Safety Monitoring Board (DSMB) it has been determined to dose the next cohort at a lower dose level in order to approach the Maximum Tolerated Dose (MTD) of SBP-101. Based on Company analysis of the safety and efficacy data from 25 patients in Cohorts 1-5, direction from the DSMB and per the approved protocol for this Phase 1a study, the next cohort of patients will consist of three patients treated at the same dose level of Cohort 4. Patients are currently being recruited for this next cohort and one patient has completed the first cycle of dosing. It is expected that this cohort of patients will be completed by August 2017.

"We are encouraged by the results we are seeing in this Phase 1a study as well as our progress in determining the MTD at this stage," said David B. Kaysen, President and CEO of Sun BioPharma. "Determining the MTD is the goal of any Phase 1a study which will allow us to proceed with the next phase of the clinical development of SBP-101."

Review of Top-Line Interim Data

“We have done a preliminary review of the patients that have been enrolled in Cohorts 1-5 of the study and are encouraged by the results we are seeing in these heavily pre-treated patients,” commented Suzanne Gagnon, M.D., Sun BioPharma’s Chief Medical Officer. “We are observing a dose-response effect on target tumor burden.”

Of the 25 patients enrolled through May 15, 2017, all but one patient had received at least two prior chemotherapy regimens. In addition to assessment of safety, 20 of the 25 patients were evaluable for preliminary signals of efficacy prior to or at the eight-week conclusion of their first cycle of treatment using the Response Evaluation Criteria in Solid Tumors (“RECIST”). Six of the 20 patients (30%) had Stable Disease (SD) and 14 of 20 (70%) had Progressive Disease (PD). It should be noted that of the 14 patients with PD, six came from Cohorts 1 and 2 and are considered to have received less than potentially therapeutic Total Cumulative Doses of SBP-101. 24 of the 25 patients had follow-up blood tests measuring the Tumor Marker CA 19-9 associated with PDA. Nine of these patients (38%) had reductions in the CA 19-9 levels, as measured at least once after the baseline assessment. Seven of the remaining 15 patients showing no reduction in CA 19-9 came from Cohorts 1 and 2.

The best response outcome and survival observed was in eight patients who received Total Cumulative Doses approximately equivalent to those of Cohorts 3 and 4. As noted above, Cohort 4 is being expanded to enroll an additional 3 patients as part of the process to determine the MTD. Seven of the eight patients in this group were evaluable for preliminary signs of efficacy at eight weeks by RECIST. Three patients (38%) had Stable Disease at week eight and four patients (57%) had reductions in the CA19-9 levels, as measured at least once after the baseline assessment. Median survival in this group was 4.1 months. Six patients (75%) have exceeded 3 months of overall survival (OS), 4 have exceeded 4 months of OS and at least 2 patients have exceeded 6 months of OS, with some patients continuing to be followed for survival.

David Kaysen commented, “Although this is a safety study, the review of this efficacy data is encouraging to all of us involved, especially when considering the stage of disease and extent of pre-treatment these patients had at the time of enrollment into the study. We are enthusiastic about moving forward to determine the MTD and to begin the next phase of the clinical trial. Again, we deeply appreciate all of the clinicians, and

especially the patients, who have participated as we continue to assess SBP-101's impact on pancreatic cancer.”

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. 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 results or expected timing 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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