



Sun BioPharma, Inc. Provides an Update on Ongoing Front-line Pancreatic Cancer Clinical Trial

- *Preliminary Efficacy Signals Seen with SBP-101 Administered in Combination with Gemcitabine and Nab-paclitaxel*
- *DSMB Approves Enrollment of 3rd and Final Cohort*

MINNEAPOLIS, MN, July 22, 2019 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today provides an update on the Company’s current clinical trial.

Front-Line Combination Pancreatic Cancer Dose Escalation Study

Following successful conclusion of the first SBP-101 dose escalation study in heavily pretreated pancreatic cancer patients that showed SBP-101 could be administered safely as monotherapy, a second Phase 1 safety study entitled, “SBP-101 Administered in Combination with Gemcitabine and Nab-paclitaxel in Newly Diagnosed Patients with Metastatic Pancreatic Ductal Adenocarcinoma” was undertaken to evaluate the addition of SBP-101 to front line gemcitabine and nab-paclitaxel treatment. Two of 3 planned cohorts receiving the combination have completed enrollment.

Following review by the Data Safety Monitoring Board of cohort 2 data, approval was received to advance to the 3rd and final planned dose level of SBP-101. To date, SBP-101, administered as a 3-drug combination, has shown no evidence of contributing to the bone marrow toxicity or peripheral neuropathy commonly seen in patients receiving gemcitabine and nab-paclitaxel treatment for pancreatic cancer.

Encouraging signals of efficacy were also noted in the second cohort. Six of 6 subjects (100%) had significant decreases in CA19-9 levels during treatment, with changes from baseline ranging from 75% to 95%. The CA19-9 level changes were accompanied by RECIST tumor assessments of 4 partial responses and 2 subjects with stable disease.

Dr. Suzanne Gagnon, Chief Medical Officer at Sun BioPharma, remarked, “Despite being an early phase study, we are excited about the response rate we are seeing in these subjects when given SBP-101 in addition to gemcitabine and nab-paclitaxel. Since prior reports in the literature have shown a positive correlation between CA19-9 decreases and overall survival, we have amended our study to follow the subjects for survival. As we continue to work with our

excellent investigators in the USA and Australia on cohort 3, we are opening additional sites in the USA in anticipation of our upcoming study expansion.”

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. 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 metastatic 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 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 and the John Flynn Private Hospital in Tugun, 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 Endowed Chair, 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. 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.

Cautionary Statement Regarding Forward-Looking Statements

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.

Contact Information:

Investor & Media Contact:

Tammy Groene – Sun BioPharma, Inc.

tgroene@sunbiopharma.com

952 479 1196