Sun BioPharma, Inc. Receives FDA Fast Track Designation for SBP-101

MINNEAPOLIS, MN, June 30, 2020 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with pancreatic cancer, today announced receipt of Fast Track Designation from the U.S. Food and Drug Administration (FDA) for its lead product, SBP-101, being developed for first-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDA) when administered in combination with gemcitabine and nab-paclitaxel.

One of FDA's Expedited Programs for Serious Conditions, Fast Track is a process designed to facilitate the development and potentially expedite the review of drugs intended to treat serious conditions and address unmet medical needs. Programs with Fast Track Designation may benefit from more frequent meetings with and written communications from FDA, in addition to being eligible for accelerated approval and priority review if certain criteria are met. Fast Track Designation also provides eligibility for a rolling review of a New Drug Application (NDA), which allows for completed sections of an NDA to be submitted for FDA review. Usually NDA review does not begin until the company has submitted the entire application to the FDA.

"Fast Track Designation is important for Sun BioPharma because it enhances our ability to develop SBP-101 as efficiently as possible," said Suzanne Gagnon, M.D., Chief Medical Officer of Sun BioPharma. Michael T. Cullen, M.D., MBA, Co-Founder, Executive Chairman, and CEO, added "There is an urgent need for new therapeutic options for patients with pancreatic cancer, and we look forward to working closely with FDA as we continue to advance our development program of SBP-101 for patients with metastatic PDA."

SBP-101 is currently being evaluated in a Phase 1a/1b clinical trial of patients with previously untreated metastatic PDA at sites in the United States and Australia. For more information please visit clinicaltrials.gov.

About SBP-101

SBP-101 is a proprietary polyamine analogue designed to be a first-in-class product to induce polyamine metabolic inhibition (PMI) by exploiting an observed high affinity of the compound for the exocrine pancreas and pancreatic ductal adenocarcinoma. The molecule has shown signals of tumor growth inhibition in clinical studies of US and Australian metastatic pancreatic cancer patients, suggesting complementary activity with an existing FDA-approved chemotherapy regimen. In clinical studies to date, SBP-101 has not shown exacerbation of the typical chemotherapy-related adverse events of bone marrow suppression and peripheral neuropathy.

The safety data and PMI profile observed in Sun BioPharma's current clinical trial provides support for continued evaluation of the compound in a randomized clinical trial.

About Sun BioPharma

Sun BioPharma Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for urgent unmet medical needs. The Company's initial product candidate is SBP-101 for the treatment of patients with metastatic pancreatic ductal adenocarcinoma, the most common type of pancreatic cancer. Sun BioPharma Inc. is dedicated to treating patients with pancreatic cancer and fully exploring SBP-101's potential for efficacy in combination with other agents and in treating other types of 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 Rochester in New York, Scripps MD Anderson Cancer Center in San Diego, California, the University of Florida, the Austin Health Cancer Trials Centre in Melbourne, Australia, the Ashford Cancer Centre in Adelaide, Australia, the Blacktown Cancer and Haemotology Centre in Sydney, Australia and the John Flynn Private Hospital in Tugun, Queensland, Australia. The Company's independent Data Safety Monitoring Board (DSMB) is Chaired by James Abbruzzese, MD, Professor of Medicine, 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," including within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "believes," "may," "expects," or "plans." Examples of forward-looking statements include, among others, statements we make regarding future determinations of the characteristics of SBP-101, and its effectiveness. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially and adversely from the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: (i) our ability to obtain additional funding to complete Phase 1 clinical trial; (ii) progress and success of our Phase 1 clinical trial; (iii) the impact of the current COVID-19 pandemic on our ability to complete enrollment in our current clinical trial; (iv) our

ability to demonstrate the safety and effectiveness of our SBP-101 product candidate (v) our ability to obtain regulatory approvals for our SBP-101 product candidate in the United States, the European Union or other international markets; (vi) the market acceptance and level of future sales of our SBP-101 product candidate; (vii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our SBP-101 product candidate; (viii) the rate of progress in establishing reimbursement arrangements with third-party payors; (ix) the effect of competing technological and market developments; (x) the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims; and (xi) such other factors as discussed in Part I, Item 1A under the caption "Risk Factors" in our most recent Annual Report on Form 10-K, any additional risks presented in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Any forward-looking statement made by us in this press release is based on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement or reasons why actual results would differ from those anticipated in any such forward-looking statement, whether written or oral, whether as a result of new information, future developments or otherwise.

Contact Information:
Investor & Media Contact:
Tammy Groene – Sun BioPharma, Inc.
952 479 1196