SUN BIOPHARMA, INC. FILES UNITED STATES PATENT PROTECTING THE MANUFACTURING PROCESS FOR ITS LEAD DRUG CANDIDATE, SBP-101

MINNEAPOLIS, MN, February 22, 2018 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB:SNBP), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today announced the acceptance by the U.S. Patent and Trademark Office of a provisional application (No. 62/623,641) for its novel manufacturing process developed for its lead drug candidate, SBP-101, currently being studied for the treatment of patients suffering from pancreatic ductal adenocarcinoma (PDA).

“This filing of a provisional patent marks a key milestone in Sun BioPharma’s Intellectual Portfolio strategy providing further protection of our proprietary manufacturing process,” said Thomas X. Neenan, PhD, Sun BioPharma’s Chief Scientific Officer. “This new process will greatly simplify the synthesis of SBP-101, reducing costs and manufacturing time as we continue to move forward with the clinical development of SBP-101 for the treatment of pancreatic cancer.”

PDA is a multi-billion dollar market, the third leading cause of cancer deaths in the US and a significant unmet medical need. SBP-101 is a novel small molecule that functions as a polyamine metabolic inhibitor. Exploiting the natural affinity of the exocrine pancreas for polyamines, SBP-101 selectively targets the cancerous cells derived from the exocrine pancreas while minimizing toxicity to pancreatic islet (insulin producing) cells and other non-target tissues. Results from an initial Phase 1 safety trial demonstrated that SBP-101 was well tolerated at dose levels below the Maximum Tolerated Dose (MTD). In addition, early signals of efficacy in the form of stable disease, reduction in the tumor marker CA19-9 and overall survival were observed in the study and the independent Data Safety Monitoring Board evaluating the study recommended further clinical development.

“As we move forward with our next clinical trial, a first-line Phase 1a/1b study of SBP-101 in combination with gemcitabine and nab-paclitaxel in previously untreated patients, this new manufacturing process positions us to produce SBP-101 to better support patient enrollment on a more timely and cost efficient basis” said David B. Kaysen, President and CEO. “The filing of this provisional patent is important next step in developing our patent portfolio and signals the importance of our commitment to develop additional patents in the future.”

About SBP-101

SBP-101 is a first-in-class, proprietary, polyamine compound designed to exert therapeutic effects in a mechanism specific to the exocrine 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 demonstrated. SBP-101 is expected to differ from current pancreatic cancer therapies in that it specifically targets tumors originating in the exocrine pancreas and has shown single-agent and combination 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 pancreatic 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 when used 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., 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 University of Minnesota, the Mayo Clinic Scottsdale, the Austin Health Cancer Trials Centre in Melbourne, Australia and the Ashford Cancer Centre in Adelaide, 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. 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

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, 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.
952 479 1196