FDA Grants SBP-101 Orphan Drug Status for Pancreatic Cancer

Sun BioPharma, Inc. announced that its lead candidate, SBP-101 has been awarded Orphan Drug Status on 7 August 2014 by the United States Food and Drug Administration. TAMPA, FL, Jan 21, 2015 (GLOBE NEWSWIRE via COMTEX) —

Sun BioPharma, Inc. (privately held), a clinical stage biopharmaceutical company developing best-in-class therapeutics for the treatment of pancreatic cancer and pancreatitis, announced today that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for SBP-101 for the treatment of patients with pancreatic cancer. SBP-101, a proprietary polyamine analogue, represents a novel approach to the treatment of pancreatic cancer. Sun BioPharma is currently completing its Investigational New Drug Application for submission to the FDA in order to initiate its clinical development program, and anticipates enrolling patients with pancreatic ductal adenocarcinoma in a Phase 1a/b clinical trial in the third quarter of 2015.

The FDA's office of Orphan Drug Products grants orphan status to support development of medicines for rare disorders defined as diseases that affect fewer than 200,000 people in the United States. Orphan drug designation provides Sun BioPharma with certain benefits, including limited market exclusivity upon regulatory approval if received, and exemption of FDA application fees and tax credits for qualified clinical trials.

"Receiving Orphan Drug Designation for SBP-101 in the treatment of pancreatic cancer is an important milestone for this clinical development program," commented Sun BioPharma's Chairman, Michael T. Cullen, MD. "SBP-101 has demonstrated superior

anti-tumor effects in treating pancreatic cancer cells that have limited sensitivity to gemcitabine or nab-paclitaxel. If the results of our Phase 1b trial and future trials show similar results, this would represent a significant advance in the treatment of patients with pancreatic cancer."