



Sun BioPharma, Inc. Summarizes SBP-101 Phase 1 Clinical Data Presented at ASCO 2020 Annual Gastrointestinal Cancers Symposium

- SBP-101 was well tolerated in combination with gemcitabine and nab-paclitaxel
- Objective Response Rate (ORR) was 62% by RECIST criteria
- Study expansion in patients with pancreatic cancer planned to begin in Q2

SAN FRANCISCO, January 24, 2020 (GLOBE NEWSWIRE) – Sun BioPharma, Inc. (OTCQB: SNBP), a clinical-stage biopharmaceutical company developing disruptive therapeutics for the treatment of people with pancreatic cancer, today summarized initial Phase 1 clinical data for SBP-101, which was presented in a poster session at the American Society for Clinical Oncology (ASCO) 2020 Gastrointestinal Cancers Symposium. SBP-101 is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI), a metabolic pathway of critical importance in cell function in multiple tumor types. Based upon the study data presented today, the adverse event profile of SBP-101 at the optimal dose level was manageable and an expansion study in patients with pancreatic ductal adenocarcinoma (PDA) is planned to begin during the second quarter of 2020.

“We are excited about the early results from this Phase 1 trial, which suggest improved activity of SBP-101 in combination with gemcitabine and nab-paclitaxel, along with a tolerable adverse event profile,” said Dr. Dusan Kotasek, Director, Clinical Research at Adelaide Cancer Centre and a key Principal Investigator in both the monotherapy and combination therapy studies of SBP-101. “Pancreatic ductal adenocarcinoma is an area of incredibly high unmet medical need, and by evaluating SBP-101 with the current standard of care, we hope to be able to offer patients an improved therapeutic option.”

Preliminary Results Demonstrate Tolerability and Clinical Activity in Metastatic Treatment-Naïve Patients

As of the data cut off date of January 4, 2020, the addition of SBP-101 to the combination of gemcitabine plus nab-paclitaxel did not increase the frequency of grade 3/4 hematologic adverse events, peripheral neuropathy, nausea or diarrhea when compared to historical control data for patients who were treated with gemcitabine plus nab-paclitaxel. The most common adverse events (all grades) attributed to treatment with SBP-101 were fatigue, elevated LFTs, and injection site pain.

The most common grade 3/4 adverse event was elevation in liver function tests, which in most cases was asymptomatic, and in all cases reversed when SBP-101 was interrupted and decreased or discontinued.

Study results in evaluable subjects enrolled in the two highest dose cohorts (N=13) demonstrated an overall response rate (ORR) of 62%, including 8 partial responses (PRs). The disease control rate (DCR) was 85% by RECIST criteria. Eleven subjects in those cohorts (69%, N=16) saw a maximum decrease in CA 19-9 of more than 60%. As of January 4, 2020, 8 of 16 subjects remained on study. Median duration of response, progression free survival and overall survival had not been reached.

Phase 1a/1b Trial Design

This ongoing multicenter, open label, Phase 1 trial enrolled 20 patients with pancreatic ductal adenocarcinoma (PDA) across three dose cohorts. Study participants received a subcutaneous dose of SBP-101 at 0.2, 0.4 or 0.6 mg/kg on days 1-5 of each 28-day cycle, in addition to intravenous doses of 1000 mg/m² of gemcitabine and 125 mg/m² of nab-paclitaxel on days 1, 8 and 15. The goal of this study was to determine a recommended dose of SBP-101 for further development. Endpoints include safety, tolerability, and pharmacokinetics, in addition to early measures of efficacy including ORR as measured by RECIST, and CA19-9 levels. Based upon preliminary safety and efficacy signals, the protocol was amended to follow subjects for progression-free survival (PFS) and overall survival (OS).

Poster Presentation Information

Efficacy of SBP-101, in combination with gemcitabine and nab-paclitaxel, in first-line treatment of metastatic pancreatic ductal adenocarcinoma.

Friday, January 24, 2020, 12:00 PM to 1:30 PM and 4:30 PM to 5:30 PM

Abstract 710, Board K21

Poster Session B: Hepatobiliary Cancer, Neuroendocrine/Carcinoid, Pancreatic Cancer, and Small Bowel Cancer

American Society for Clinical Oncology (ASCO) 2020 Gastrointestinal Cancers Symposium

About SBP-101

SBP-101 is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI), a metabolic pathway of critical importance in multiple tumor types. Sun BioPharma licensed SBP-101 from the University of Florida Research Foundation in 2011. The molecule has been shown to be a highly effective tumor growth inhibitor in preclinical studies of human pancreatic cancer models, demonstrating superior and complementary activity to existing FDA-approved chemotherapy agents. SBP-101 has demonstrated activity against primary and metastatic disease in clinical trials of patients with pancreatic cancer. The safety data and PMI profile observed in Sun BioPharma's previously

completed first-in-human dose escalation study of SBP-101 provides support for evaluation of SBP-101 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. Sun BioPharma's development program is currently targeting pancreatic cancer; its initial product candidate is SBP-101 for the potential treatment of patients with metastatic pancreatic cancer. 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 Haematology Centre in Sydney, Australia and the John Flynn Private Hospital in Tugun, Queensland, Australia. Sun BioPharma'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 SBP-101, and plans with respect to the initiation of additional clinical trials, including a Phase 2 study. 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. As with any pharmaceutical product like SBP-101, there are substantial risks and uncertainties in the process of development and commercialization. There can be no guarantees that this treatment will receive regulatory approval or, if approved, will achieve the intended benefits or become commercially successful. 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 those indicated in 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) the anticipated timing of first patient enrollment, (ii) our need to obtain additional capital, which may not be available on acceptable terms or at all, (iii) risks inherent in the development and/or commercialization of potential products, and (iv) uncertainty in the results or timing of clinical trials or regulatory approvals. Any forward-looking statement made by us in this press release is based only 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.

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