Panbela Presents Clinical Data on Phase 1b Clinical Trial of SBP-101 in Combination with Gemcitabine and Nab-Paclitaxel in Patients with Metastatic PDA at 2021 ASCO Annual Meeting

MINNEAPOLIS (GLOBE NEWSWIRE) – June 4, 2021 - Panbela Therapeutics, Inc. (Nasdaq: PBLA), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with cancer today announced the presentation of interim clinical data from its Phase 1b combination therapy study of SBP-101, a proprietary polyamine analogue, with gemcitabine and nab-paclitaxel (G+A) in patients with metastatic Pancreatic Ductal Adenocarcinoma (PDA), at the American Society of Clinical Oncology (ASCO) Annual Meeting taking place June 4-8, 2021.

Jennifer K. Simpson, PhD, MSN, CRNP President & Chief Executive Officer of Panbela Therapeutics, commented, “We are excited to share interim data from cohort 4 and the expansion. Optimal dosing regimens were explored and the signals of efficacy reported support continued development of SBP-101 as an addition to first-line treatment for advanced PDA and as neo-adjuvant treatment for patients with potentially resectable disease.”

“The conclusion of the poster is that SBP-101 may enhance first-line treatment with gemcitabine and nab-paclitaxel patients with metastatic PDA. We are encouraged by this conclusion even under sub-optimal conditions, including dose interruptions, which confounded results. Cohorts 2 and 3 did not have the dose interruptions that cohort 4 had, and cohort 2 had an objective response rate of 71%,” continued Dr. Simpson. “We look forward to initiating a randomized phase 2 study in metastatic PDA mid-year.”

In the response-evaluable subjects in cohort 4 + Phase 1b (N=29), 11 had treatment with SBP-101 interrupted to evaluate retinal toxicity; this may impact final efficacy results. In cohort 2 (N=7) the objective response rate (ORR) was 71%, and the disease control rate (DCR) was 100% by RECIST criteria (stable disease (SD) or better for ≥ 16 weeks). Median progression free survival (PFS) in cohort 2 was 5.63 months and median overall survival (OS) was 10.3 months compared with ORR of 48%, DCR of 70%, PFS of 5.2 months and median OS, not yet reached, in cohort 4 + 1b.

SBP-101 was well-tolerated when administered at doses and schedules tested in combination with G+A in subjects with previously untreated metastatic pancreatic adenocarcinoma. The most common Grade ≥3 adverse events (AEs) related to any study medication were
neutropenia in 20 subjects (19 attributed to G+A and 1 attributed to all 3) and elevated liver function tests in 15 subjects (5 attributed to SBP-101 and 10 attributed to all 3). SBP-101-related increases in LFTs were asymptomatic in all but 2 subjects and reversed in all subjects when SBP-101 administration was interrupted and dose-reduced or discontinued. Additionally, six subjects experienced serious vision adverse events (3 possibly related to SBP-101, 1 related to gemcitabine and 2 related to all 3 based on PI assessment). All were considered by the sponsor to be possibly related to SBP-101; 5 had findings consistent with retinopathy. All future studies will exclude patients with a history of retinopathy or at risk of retinal detachment and scheduled ophthalmologic monitoring for all patients. Additionally, in future dose-finding studies screening for retinal toxicity will be included.

The company continues to plan for the initiation of a randomized trial to study SBP-101, as an addition to first-line treatment for metastatic PDA, in the middle of this year and releasing preclinical data across tumors outside of pancreatic cancer by year-end.

Additional meeting information can be found on the ASCO website at https://meetings.asco.org/am/attend. After presenting at ASCO, the poster will be available on the company's website at the end of day on June 8, 2021.

**About SBP-101**

SBP-101 is a proprietary polyamine analogue designed to induce polyamine metabolic inhibition (PMI) by exploiting an observed high affinity of the compound for pancreatic ductal adenocarcinoma and other tumors. The molecule has shown signals of tumor growth inhibition in clinical studies of US and Australian metastatic pancreatic cancer patients, suggesting potential complementary activity with an existing FDA-approved standard chemotherapy regimen. In data evaluated from clinical studies to date, SBP-101 has not shown exacerbation of bone marrow suppression and peripheral neuropathy, which can be chemotherapy-related adverse events. Recently observed serious visual adverse events are being evaluated and patients with a history of retinopathy or at risk of retinal detachment will be excluded from future SBP-101 studies. The safety data and PMI profile observed in the current Panbela sponsored clinical trial generally provides potential support for continued evaluation of SBP-101 in a randomized clinical trial. For more information, please visit https://clinicaltrials.gov/ct2/show/NCT03412799.

**About Panbela**

Panbela Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for patients with urgent unmet medical needs. The company's initial product
candidate, SBP-101, is for the treatment of patients with metastatic pancreatic ductal adenocarcinoma, the most common type of pancreatic cancer. Panbela Therapeutics, Inc. is dedicated to treating patients with pancreatic cancer and exploring SBP-101’s potential for efficacy in combination with other agents and in treating other types of cancer. Further information can be found at www.panbela.com. Panbela Therapeutics, Inc. common stock is listed on The Nasdaq Stock Market LLC under the symbol PBLA.

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,” “expect,” “intend,” “may,” and “plan.” Examples of forward-looking statements include statements we make regarding the timing and potential results of future clinical trials. 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 a randomized 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 monitoring and reporting 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.

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