



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 2022 ASCO GI Meeting

- *Interim data presented in poster reflects median overall survival of 12.0 months, not yet final, and an objective response rate of 48%, both greater than historical rates reported for standard of care*

MINNEAPOLIS (GLOBE NEWSWIRE) – January 23, 2022 -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 in patients with metastatic pancreatic ductal adenocarcinoma (PDA), at the American Society of Clinical Oncology (ASCO) Gastrointestinal (GI) Meeting that took place January 20-22, 2022.

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. A median overall survival (OS) of 12.0 months which is not yet final, and an objective response rate (ORR) of 48%, both exceeded historical rates reported for gemcitabine + nab paclitaxel and supports the 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 abstract 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 intend to continue development of SBP-101 and look forward to executing our global randomized phase 2 study in metastatic PDA.”

At the Phase 1b dose and schedule (N=30), CA19-9 levels decreased 60-99% in 70% of evaluable patients, with 1/29 (3%) achieving a complete remission, 13/29 evaluable patients achieving partial responses (45%) and 10/29 achieving stable disease at 8 weeks (34%). PFS was 6.0 months. While PFS may be confounded by SBP-101 dosing holds implemented to investigate potential toxicity, the rates for 6-month PFS was 52% and for 12 month PFS was 10%. Nine subjects are in survival follow up as of the date the poster was presented at the ASCO GI meeting. Median OS is 12.0 months and is not final.

The safety population includes all subjects who received at least one dose of SBP-101 (N=50). 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 14 subjects (5 attributed to SBP-101 and 9 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, seven subjects experienced serious vision adverse events (4 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.

The company has just begun a randomized trial to study SBP-101, as an addition to first-line treatment for metastatic PDA, will begin a neoadjuvant pancreatic trial this quarter and will begin an Ovarian Cancer program mid-year.

Additional meeting information can be found on the ASCO website at <https://meetings.asco.org/gi/>. After presenting at ASCO GI, the poster will be available on the company's [website](#) on January 24, 2022.

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 potential 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, if SBP-101 receives approval in the US. 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. Serious visual adverse events observed in the Company's recently completed Phase 1a/1b clinical trial have been 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 provides 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 in other cancer indications. 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: “believe,” “expect,” “intend,” “may,” and “plan.” Examples of forward-looking statements include statements we make regarding our approximate enrollment period. 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 and procure the active ingredient; (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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