

Panbela Initiates a Randomized, Double-Blind, Placebo-Controlled Study (ASPIRE) of Nab-Paclitaxel and Gemcitabine With or Without SBP-101 in Subjects Previously Untreated for Metastatic Pancreatic Ductal Adenocarcinoma

MINNEAPOLIS (GLOBE NEWSWIRE) - January 26, 2022, Panbela Therapeutics, Inc. (Nasdaq: PBLA), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with cancer, today announced the initiation of the company's global Phase 2 clinical trial of SBP-101 in combination with Gemcitabine and Nab-Paclitaxel in patients with metastatic pancreatic ductal adenocarcinoma, which is referred to as the ASPIRE trial.

Arvind Chaudhry MD, PhD, Principal Investigator at Summit Cancer Centers in Spokane, Washington was the first clinical site activated, with approximately 60 additional sites expected to be activated in 2022. Panbela has commenced screening for eligible patients, with enrollment expected to complete in approximately 12 months.

The ASPIRE trial is designed as a randomized double-blind placebo-controlled trial, with a primary endpoint of overall survival. The design includes a futility analysis after 104 progression-free survival events. Panbela is seeking to conduct the trial at leading cancer centers in the United States, Europe, and the Asia-Pacific region.

"Pancreatic cancer is one of the most common causes of cancer deaths in the United States and represents a significant unmet medical need, as is underscored by SBP-101's Fast Track and Orphan Drug designations," said Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer. "We are enthusiastic about having initiated the ASPIRE global randomized Phase 2 trial. Given the rigor of the trial design, we expect the resulting data to support our registration effort."

## **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 SPB-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 <a href="https://clinicaltrials.gov/ct2/show/NCT03412799">https://clinicaltrials.gov/ct2/show/NCT03412799</a>.

## **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: "design," "expect," "may," "plan," "potential," and "seek." Examples of forward-looking statements include statements we make regarding timing of enrollment and conduct of the ASPIRE trial, participating sites, and outcomes. 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 this randomized clinical trial; (ii) completion and success of our Phase 1 clinical trial; (iii) the impact of the current COVID-19 pandemic on our ability to initiate clinical sites and complete enrollment in this 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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