



## **Panbela Provides Update on Current Clinical Trial: Decision to Hold Administration of SBP-101**

- Panbela is studying patients with pancreatic cancer testing investigative agent SBP-101 when used in combination with standard of care agents gemcitabine and nab-paclitaxel
- Panbela's independent data safety monitoring board (DSMB) recommended SBP-101 be held for ongoing patients in order to obtain additional safety information but will continue with the standard drug regimen
- All other trial activities continue

**MINNEAPOLIS, Feb 10, 2021** (GLOBE NEWSWIRE) -- Panbela Therapeutics, Inc. (Nasdaq: PBLA), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with cancer, in its pursuit to meet the urgent need for new therapeutic options for patients with pancreatic cancer, has been evaluating the safety and tolerability of SBP-101 when used in combination with standard of care agents gemcitabine and nab-paclitaxel for first-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDA).

SBP-101 has received Fast Track and Orphan Drug designation from FDA and Panbela has been working closely with the FDA to advance its development studies of SBP-101 for patients with metastatic PDA.

### **What We Know Now**

Panbela continues to be in communication with the trial investigators regarding the recommendation from the independent data safety monitoring board (DSMB) of the ongoing Phase 1 clinical trial to hold administration of SBP-101 pending further investigation of visual disturbance adverse events.

Some patients in the trial were noted to have complaints of visual changes, although visual changes were not seen in the SBP-101 monotherapy study. We have consulted with the DSMB and SBP-101 will not be administered to ongoing patients in the current trial while additional safety information is analyzed. Patients will continue with the standard drug regimen. All other trial activities continue. Panbela has conferred with FDA regarding the plan to continue the trial but hold dosing of SBP-101 in ongoing patients until we can learn more. Withholding SBP-

101 constitutes a “partial clinical hold”. There is no impact on enrollment, as enrollment of the trial completed in December 2020, and the study is ongoing.

### **Next Steps**

Panbela is working to finalize a visual screening program in order to understand the significance of reported visual changes and to inform future studies. We will also seek to evaluate the exact cause of these recent visual reports and to determine whether serial eye exams during treatment can identify potential toxicity or risk before symptoms develop.

While we evaluate supplementary data, we remain confident in the potential benefits of SBP-101 including its potential benefits for patients with pancreatic cancer. We are thankful to the patients who have, or are, participating in our clinical trials. We are committed to objectively evaluating the data from those clinical studies to confirm both the therapeutic benefits and safety profile of our polyamine inhibitor in metastatic pancreatic cancer patients.

Panbela is planning to submit interim results at a major cancer conference and looks forward to publication of final efficacy and safety data, when available.

Additionally, all other research and manufacturing activities related to future SBP-101 indications are continuing, including working with the FDA to initiate a randomized trial mid-year.

### **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 complementary activity with an existing FDA-approved standard chemotherapy regimen. In clinical studies to date, SBP-101 has not shown exacerbation of the typical chemotherapy-related adverse events of bone marrow suppression and peripheral neuropathy. The safety data and PMI profile observed in the current Panbela sponsored current clinical trial generally provides support for continued evaluation of the compound in a randomized clinical trial subject to Panbela’s submission of a complete response and the FDA’s removal of the partial clinical hold. 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](http://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," "continue," "dedicated," "expect," "intend," "may," "plan," and "seek." Examples of forward-looking statements include, among others, statements we make regarding future determinations of the characteristics of SBP-101 and its effectiveness, removal of the partial clinical hold, publication of results, other trial activities and the timing of the same. 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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