## Panbela Announces First Patient Enrolled in its Aspire Trial Studying SBP-101 in Combination with Gemcitabine and Nab-Paclitaxel in Patients with Metastatic Pancreatic Ductal Adenocarcinoma

- *Expects interim data by early 2024*

**MINNEAPOLIS, Aug. 11, 2022 (GLOBE NEWSWIRE) Panbela Therapeutics, Inc. (Nasdaq: PBLA),** a clinical stage company developing disruptive therapeutics for the treatment of patients with urgent unmet medical needs, today announced it has enrolled the first patient in its global clinical trial to study SBP-101 in combination with Gemcitabine and Nab-Paclitaxel in patients with metastatic pancreatic ductal adenocarcinoma, which is referred to as the ASPIRE trial, a randomized double-blind placebo-controlled trial, with a primary endpoint of overall survival. Detailed information on the trial can be located at https://clinicaltrials.gov/ct2/show/NCT05254171.

"While site initiation was gradual, we are pleased with the current momentum of the ASPIRE trial. We expect that a significant number of global sites will be open by year-end with the full complement of sites open by the first quarter 2023. Australia opened last week with the first site activated within the country, and now they've enrolled the first patient into the study," commented, Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer of Panbela. "Australian study centers have been wonderful to work with and were important contributors to our phase 1 trial, enrolling a heavy preponderance of the 50 patients. We're excited to reach this milestone of first patient enrolled, as we move forward towards interim analysis which is expected to complete in early 2024."

Australia marked the second country activated for the ASPIRE trial, and first to enroll, with approximately 90 additional sites expected to be activated across 10 countries by early 2023.

Additionally, in response to European and FDA regulatory feedback, the study was amended to include the total trial sample size (600 subjects) and the design modified to utilize overall survival as the primary endpoint to be examined at an interim analysis. While the trial is expected to take approximately 36 months to fully enroll, the interim analysis is still expected to occur in early 2024.

**About our Pipeline**

The pipeline consists of assets currently in clinical trials with an initial focus on familial adenomatous polyposis (FAP), first-line metastatic pancreatic cancer, neoadjuvant pancreatic

cancer, colorectal cancer prevention and ovarian cancer. The combined development programs have a steady cadence of catalysts with programs ranging from pre-clinical to registration studies.

**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, demonstrating a median overall survival (OS) of 14.6 months which is final, and an objective response rate (ORR) of 48%, both exceeding what is seen typically with the standard of care of gemcitabine + nab-paclitaxel suggesting potential complementary activity with the 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. Serious visual adverse events 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 .**

**Flynpovi ™**

Flynpovi is a combination of CPP-1X (eflornithine) and sulindac with a dual mechanism inhibiting polyamine synthesis and increase polyamine export and catabolism. In a Phase 3 clinical trial in patients with sporadic large bowel polyps, the combination prevented > 90% subsequent pre-cancerous sporadic adenomas versus placebo. Focusing on FAP patients with lower gastrointestinal tract anatomy in the recent Phase 3 trial comparing Flynpovi to single agent eflornithine and single agent sulindac, FAP patients with lower GI anatomy (patients with an intact colon, retained rectum or surgical pouch), Flynpovi showed statistically significant benefit compared to both single agents ($p \leq 0.02$) in delaying surgical events in the lower GI for up to four years. The safety profile for Flynpovi did not significantly differ from the single agents and supports the continued evaluation of Flynpovi for FAP.

**CPP-1X**

CPP-1X (eflornithine) is being developed as a single agent tablet or high dose power sachet for several indications including prevention of gastric cancer, treatment of neuroblastoma and recent onset Type 1 diabetes. Preclinical studies as well as Phase 1 or Phase 2 investigator-initiated trials suggest that CPP-1X treatment is well tolerated and has potential activity.

**About Panbela**

Panbela Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing disruptive therapeutics for patients with urgent unmet medical needs. The company's lead assets are SBP-101 and Flynpovi 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," "design," "expect," "feel," "intend," "may," "plan," "scheduled," and "will." Examples of forward-looking statements include statements we make regarding results of collaborations with third parties and future studies. All statements other than statements of historical fact are statements that should be deemed forward-looking statements. 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 execute our business and clinical development plans; (ii) progress and success of our clinical development program; (iii) the impact of the current COVID-19 pandemic on our ability to conduct our clinical trials; (iv) our ability to demonstrate the safety and effectiveness of our product candidates: SBP-101 and eflornithine (v) our reliance on a third party for the execution of the registration trial for our product candidate Flynpovi; (vi) our ability to obtain regulatory approvals for our product candidates, SBP-101 and eflornithine in the United States, the European Union or other international markets; (vii) the market acceptance and level of future sales of our product candidates, SBP-101 and eflornithine; (viii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our product candidates, SBP-101 and eflornithine; (ix) the rate of progress in establishing reimbursement arrangements with third-party payors; (x) the effect of competing technological and market developments; (xi) 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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