



Panbela Announces Adoption of Commission Implementing Decision from the EMA for the Orphan Designation of Ivospemin (SBP-101) in Combination with Gemcitabine and Nab-Paclitaxel in Patients with Metastatic Pancreatic Ductal Adenocarcinoma

MINNEAPOLIS, Jan. 19, 2023 (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 that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products has issued the Adoption of Commission Implementing Decision relating to the designation of ivospemin (SBP-101) as an orphan medicinal product in combination with gemcitabine and nab-Paclitaxel in patients with metastatic pancreatic ductal adenocarcinoma (PDA). The Commission adopted the decision on January 13, 2023 and it will be published for information in all official languages of the EU in the Community Register of Orphan Medicinal Products (<http://ec.europa.eu/health/documents/community-register/html/orphreg.htm>). Previously, the U.S. Food and Drug Administration (FDA) granted orphan drug designation to SBP-101.

“We are pleased to receive notice that the European Commission has adopted the positive decision for orphan drug designation from EMA’s Committee for Orphan Medicinal Products,” said Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer of Panbela. “The designation of orphan drug status within the EU is an important achievement as we continue to advance the global ASPIRE trial with the potential that this may be an option for patients with first line metastatic pancreatic cancer in the future.”

Orphan drug designation in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products. The EMA’s orphan designation is available to companies’ developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the EU. Medicines that meet the EMA’s orphan designation criteria may qualify for financial and regulatory incentives, including a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase and access to centralized marketing authorization.

Panbela is continuing to focus on site initiation and enrollment in the ASPIRE trial to ultimately deliver a more effective treatment for pancreatic cancer, a deadly disease with few treatment options. The Company expects that the full complement of sites will be open by mid 2023.

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 Ivospemin

Ivospemin 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. It has shown signals of tumor growth inhibition in clinical studies of metastatic pancreatic cancer patients, demonstrating a median overall survival (OS) of 14.6 months and an objective response rate (ORR) of 48%, both exceeding what is typical for 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, ivospemin 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 previous Panbela-sponsored clinical trials provide support for continued evaluation of ivospemin in the ASPIRE 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 may be 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. Panbela's lead assets are

Ivospemin (SBP-101) and Flynnpovi. Further information can be found at www.panbela.com. Panbela's 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: "aim," "anticipate," "believe," "design," "expect," "feel," "focus," "intend," "may," "plan," "potential," "scheduled," and "will." Examples of forward-looking statements include statements we make regarding results of collaborations with third parties, future milestones 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: ivospemin (SBP-101) and eflornithine (CPP-1X); (v) our reliance on a third party for the execution of the registration trial for our product candidate Flynnpovi; (vi) our ability to obtain regulatory approvals for our product candidates, SBP-101 and CPP-1X 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 CPP-1X; (viii) the cost and delays in product development that may result from changes in regulatory oversight applicable to our product candidates, SBP-101 and CPP-1X; (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; (xii) our ability to maintain the listing of our common stock on a national securities exchange; and (xiii) 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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