

Panbela Announces Oral Presentation at Digestive Disease Week (DDW): Evaluation of the Safety and Efficacy of Eflornithine (Difluoromethylornithine, DFMO) in Patients with Gastric Premalignant Conditions in the High Incidence Areas of Latin America

MINNEAPOLIS, June 10, 2024, (GLOBE NEWSWIRE) -- **Panbela Therapeutics, Inc**. (OTCQB: PBLA), a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with cancer, today announces an oral presentation at the Digestive Disease Week (DDW) conference, which was held May 18-21, 2024. The work reflects the Company's on-going collaboration with Vanderbilt University Medical Center.

"Gastric adenocarcinoma is the fifth leading global cause of cancer mortality and leading infection-associated cancer. In the U.S., gastric adenocarcinoma represents a major cancer disparity, with incidence rates 2-3 times or more greater in all non-white populations. Patients with gastric premalignant conditions, intestinal metaplasia and atrophic gastritis, represent a high unmet need for chemopreventative approaches," said Dr. Douglas R. Morgan, UAB Division of Gastroenterology and Hepatology, The University of Alabama at Birmingham, AL and Dr. Keith T. Wilson, Division of Gastroenterology and Hepatology, Vanderbilt University Medical Center, Nashville, TN.

A National Cancer Institute funded, Phase IIa placebo-controlled Randomized Clinical Trial of eflornithine in patients with gastric premalignant conditions was conducted between September 2016 and December 2022 in rural Honduras and Puerto Rico and was an oral presentation at DDW by Dr. Wilson on May 21, 2024. *H. pylori* (Hp) positive and negative subjects ages 30-60 were treated with eflornithine or placebo for 18 months, with endoscopy at baseline, and 6, 18, and 24 months. At baseline, 80% of subjects were Hp positive, and 46% and 54% had global histology of atrophy and intestinal metaplasia, respectively. A total of 78, 69, and 55 patients reached the 6-month primary outcome, the end-of-treatment 18 month (EoT), and the end-of-study (EoS) 24 month time points, respectively. Eflornithine treatment was safe and well-tolerated. Overall grade 1-2 adverse events (AEs) were greater in the placebo group (108 vs 81) and grade 3 AEs were also higher in the placebo (3 vs 1). The results of the study demonstrated that eflornithine reduced DNA damage long-term in patients after completing treatment, as measured by pH2AX immunostaining, a DNA damage marker was significantly lower at the 24 month vs. 18 month time point in the eflornithine group and unchanged in the placebo group.

"Panbela's focus on the polyamine pathway has implications for both the prevention and treatment of cancer. It is established that pro-tumorigenic and cancer cells are highly dependent on polyamines for survival and the ability of effornithine to reduce gastric epithelial cell DNA damage may have implications for prevention in those patients at high risk for developing infection-associated gastric cancer," said Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer of Panbela.

Details of the presentation are as follows:

Oral Presentation

Title: Evaluation of the Safety and Efficacy of Eflornithine (Difluoromethylornithine, DFMO) in Patients with Gastric Premalignant Conditions in the High Incidence Areas of Latin America

Session Type: Research Forum

Session Title: Chemoprevention for GI Cancers: Drugs and/or Bugs

Session Date and Time: May 21, 2024 from 2:00 PM to 3:30 PM EDT (UTC -4)

Additional meeting information can be found on the DDW website: https://eppro02.ativ.me/src/EventPilot/php/express/web/planner.php?id=DDWLITE24

The abstract will also be available on the Company's website at **https://panbela.com/events-presentations/** once the information has been released by DDW.

About Panbela's 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 anticipated catalysts with programs ranging from pre-clinical to registration studies.

Ivospemin (SBP-101)

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.

Flynpovi ™

Flynpovi is a combination of CPP-1X (eflornithine) and sulindac with a dual mechanism inhibiting polyamine synthesis and increasing polyamine export and catabolism. In a Phase III

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 III trial comparing Flynpovi to single agent effornithine and single agent sulindac, FAP patients with lower GI anatomy (patients with an intact colon, retained rectum or surgical pouch), showed statistically significant benefit compared to both single agents ($p \le 0.02$) 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 (effornithine) is being developed as a single agent tablet or high dose powder sachet for several indications including prevention of gastric cancer, treatment of neuroblastoma and recent onset Type 1 diabetes. Preclinical studies as well as Phase I or Phase II 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 Flynpovi. Further information can be found at **www.panbela.com**. Panbela's common stock is eligible for quotation on the OTCQB 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: "anticipate," "believe," "can," "design," "expect," "focus," "intend," "looking forward," "may," "plan," "positioned," "potential," and "will." 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 Flynpovi ; (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 obtain a listing of our common stock on a national securities exchange; and (xii) 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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