



## **Panbela Therapeutics to Receive a Total Up to \$9.5 Million for Divestiture of Assets within Eflornithine (DFMO) Pediatric Neuroblastoma Program to US WorldMeds**

**MINNEAPOLIS and LOUISVILLE, July 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 it has divested certain assets in its eflornithine pediatric neuroblastoma program to **US WorldMeds<sup>®1</sup>** (USWM), a Kentucky-based specialty pharmaceutical company.

Neuroblastoma, a rare cancer originating from immature nerve cells, contributes to nearly 15% of pediatric cancer deaths.<sup>[1]</sup> Panbela Therapeutics' subsidiary, Cancer Prevention Pharmaceuticals, has extensively collaborated with leading neuroblastoma research groups such as the Neuroblastoma Medulloblastoma Translational Research Consortium (NMTRC) (now Beat Childhood Cancer), New Advances in Neuroblastoma Therapy (NANT), the Children's Oncology Group (COG), and the National Cancer Institute (NCI) in the clinical development of eflornithine as a treatment for neuroblastoma. These collaborative efforts, spanning multiple years, have resulted in the Company receiving orphan drug designations for the use of eflornithine in the treatment of neuroblastoma in both the United States and Europe.

Under the terms of the agreement, Panbela is entitled to receive up to approximately \$9.5 million non-dilutive funding in exchange for the sale of certain assets within its pediatric neuroblastoma program for eflornithine. Panbela will receive payments upon USWM's successful completion of milestones related to eflornithine's clinical development, regulatory approval, and commercial sales.

"Divesting eflornithine assets for pediatric neuroblastoma is another milestone in executing our business plan to generate long-term value for our shareholders. US WorldMeds' existing focus in neuroblastoma makes them an ideal company to further its clinical development in that indication," said Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer of Panbela. "This agreement further expands our portfolio of partner-funded programs and has the potential to generate considerable development milestone payments. We welcome US WorldMeds to our portfolio of partners who continue the development of our product candidates."

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<sup>1</sup> US WORLDMEDS is a registered trademark of USWM, LLC.

"We are excited that the agreement will help address this high unmet need through the further development of eflornithine for the treatment of patients with neuroblastoma," said Elizabeth Bruckheimer, Ph.D., Vice President & Chief Scientific Officer of Panbela. "After investigating the role of polyamines and the therapeutic potential of eflornithine in neuroblastoma for many years, it is comforting to be passing the baton to the capable hands at USWM. We look forward to helping USWM with the ongoing FDA review of their New Drug Application for eflornithine and future research efforts for patients with neuroblastoma."

"This transaction strengthens and expands our neuroblastoma program data currently under FDA review and builds upon our established partnerships to fully unleash the potential of DFMO as a breakthrough treatment for neuroblastoma," commented Paul Breckinridge Jones, Chief Executive Officer of US WorldMeds. "Our agreement with Panbela supports our overarching objective of redefining the standard of care and significantly improving outcomes for children with this devastating disease, who are in urgent need of new therapies."

### **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), Flynnpovi 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 Flynnpovi did not significantly differ from the single agents and supports the continued evaluation of Flynnpovi for FAP.

### **CPP-1X Eflornithine**

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](http://www.panbela.com). Panbela's common stock is listed on The Nasdaq Stock Market LLC under the symbol "PBLA".

### **About US WorldMeds**

US WorldMeds (USWM) is a privately held specialty pharmaceutical company whose treatment options are making a difference in the lives of the patients and communities it serves. USWM takes an agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, USWM has a global presence and more than 20 years of experience in the development, licensure, and commercialization of unique pharmaceutical products. For more information about USWM, visit [www.usworldmeds.com](http://www.usworldmeds.com).

### **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," "design," "may," "plan," and "will." Examples of forward-looking statements include statements we make regarding timing of trials and 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: 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 Flynnovi ; (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; 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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