



## **Panbela Announces Issuance of New Patent in China for Claims of a Novel Process for the Production of SBP-101**

Patent developed in collaboration with Syngene International Ltd.

**MINNEAPOLIS, September 26, 2023, (GLOBE NEWSWIRE) Panbela Therapeutics, Inc.** (Nasdaq: PBLA), a clinical-stage biopharmaceutical company developing disruptive therapeutics for the treatment of patients with urgent unmet medical needs, today announced an Issue Notification for the Chinese patent 201980010826.7 titled “METHODS FOR PRODUCING (6S,15S)-3,8,13,18-TETRAAZAICOSANE-6,15-DIOL”. This patent, developed in collaboration with Syngene International Ltd., an integrated research, development, and manufacturing services company, claims a novel process with a reduced number of synthetic steps from seventeen to six to produce SBP-101 (ivospemin), a lead investigational product. The patent is valid until 2039.

Jennifer K. Simpson, PhD, MSN, CRNP, President & Chief Executive Officer of Panbela Therapeutics, commented, “This expansion of coverage into China and Asia as a whole, is significant for our patent portfolio and aligns with our global clinical programs. With a shorter synthesis of SBP-101, there are several advantages including a more scalable, efficient, and cost-effective manufacturing process. These benefits are essential for future efforts, as they can potentially reduce production costs and improve the overall competitiveness of SBP-101 in the market.

Jonathan Hunt, Managing Director and Chief Executive Officer, Syngene International Ltd., said, “We are delighted with the continued success of our longstanding collaboration with Panbela. Our partnership with them dates back to 2013 and since then we have collaborated on multiple projects. In this case, streamlining the production process of an investigational product is a core expertise in our Development Services division. A simpler production process means that commercialization will be easier, and the drug will reach patients more quickly. The protection of SBP-101 production through patents in multiple markets and now in China are significant milestones.”

Dr. Simpson added, “This achievement underscores the Company’s commitment to protecting its intellectual property, advancing its products on a global scale, which can potentially lead to a broader market access and increased opportunities for SBP-101’s success.”

### **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, ovarian cancer and diabetes. 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 / 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 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 Flynpovi. 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 Syngene**

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science,

robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA. For more details, visit [www.syngeneintl.com](http://www.syngeneintl.com). For the Company's latest Environmental, Social, and Governance (ESG) report, visit <https://esgreport.syngeneintl.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) our lack of diversification the corresponding risk of an investment in our Company; (iii) our ability to maintain our listing on a national securities exchange; iv) progress and success of our clinical development program; (v) our ability to demonstrate the safety and effectiveness of our product candidates: ivospemin ( SBP-101 ), Flynpovi, and eflornithine (CPP-1X) (v) our ability to obtain regulatory approvals for our product candidates, SBP-101, Flynpovi 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, Flynpovi 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, Flynpovi 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 (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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