



# Investor Presentation

January 2024

Last modified  
January 16, 2024

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This presentation includes information about investigational agents. The efficacy and safety of such investigational agents have not yet been established. Drug development is uncertain and investigative agents may be terminated along the development process.

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# Company Presents A Unique Opportunity: Multi-Targeted Approach to Reset Dysregulated Biology

Scientific focus on polyamines, key regulators of normal biology altered in many disease states

1

- Company focus on polyamine targeted platform spanning multiple indications
- Polyamine targeted therapy established in oncology with recent eflornithine approval

2

- Pipeline spans from pre-clinical to Phase III registration programs

3

- Approximately a \$5 Billion aggregate market potential across lead indications

4

- Multiple near term inflection points
- CPP acquisition completed in 2022 to create complementary, multiproduct, multi-indication portfolio

5

- Strategic synergies and partnerships (NCI, SWOG, JDRF, JHU SOM, MDACC, Moffitt)

Combined clinical program pipeline to create significant shareholder value

# Highly Experienced Management Team with Proven Track Record

Proven orphan and oncology drug discovery, development and commercialization expertise



**Dr. Jennifer Simpson**  
*Chief Executive Officer*

**15+ Years**



**Sue Horvath**  
*Chief Financial Officer*

**15+ Years**



**Dr. Elizabeth Bruckheimer**  
*VP, Chief Scientific Officer*

**14+ Years**



**Rachel Bragg**  
*VP, Clinical Development*

**14+ Years**

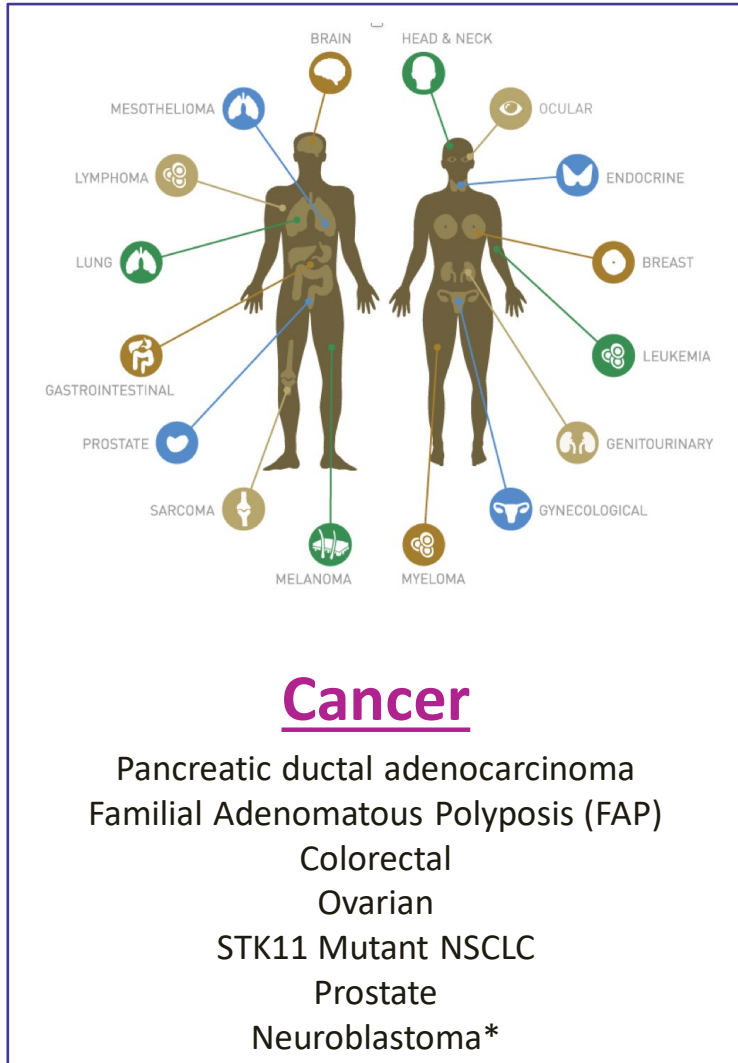


**Dr. Ashok Chavan**  
*VP, CMC, QA, Supply Chain*

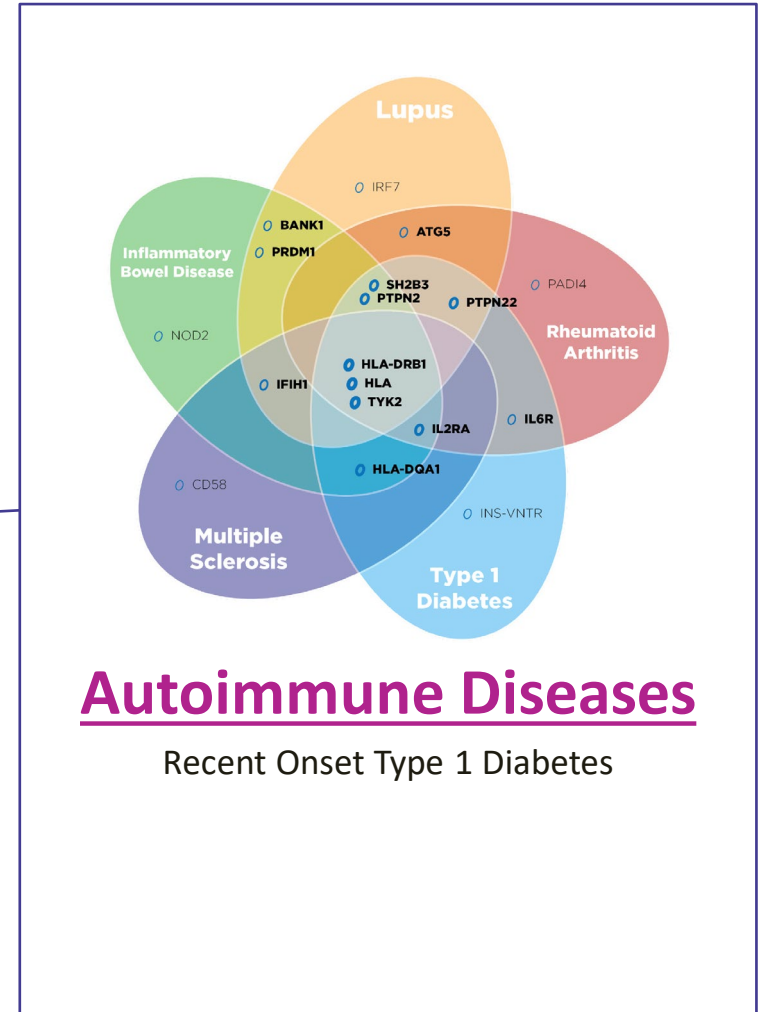
**15+ Years**

Team collectively has 10+ FDA approvals and decades of Pharma experience positioning Panbela to execute on the clinical development programs

# Dysregulation of the Polyamine Pathway Leads to Disease



**Polyamine  
Dysregulation  
in Disease**



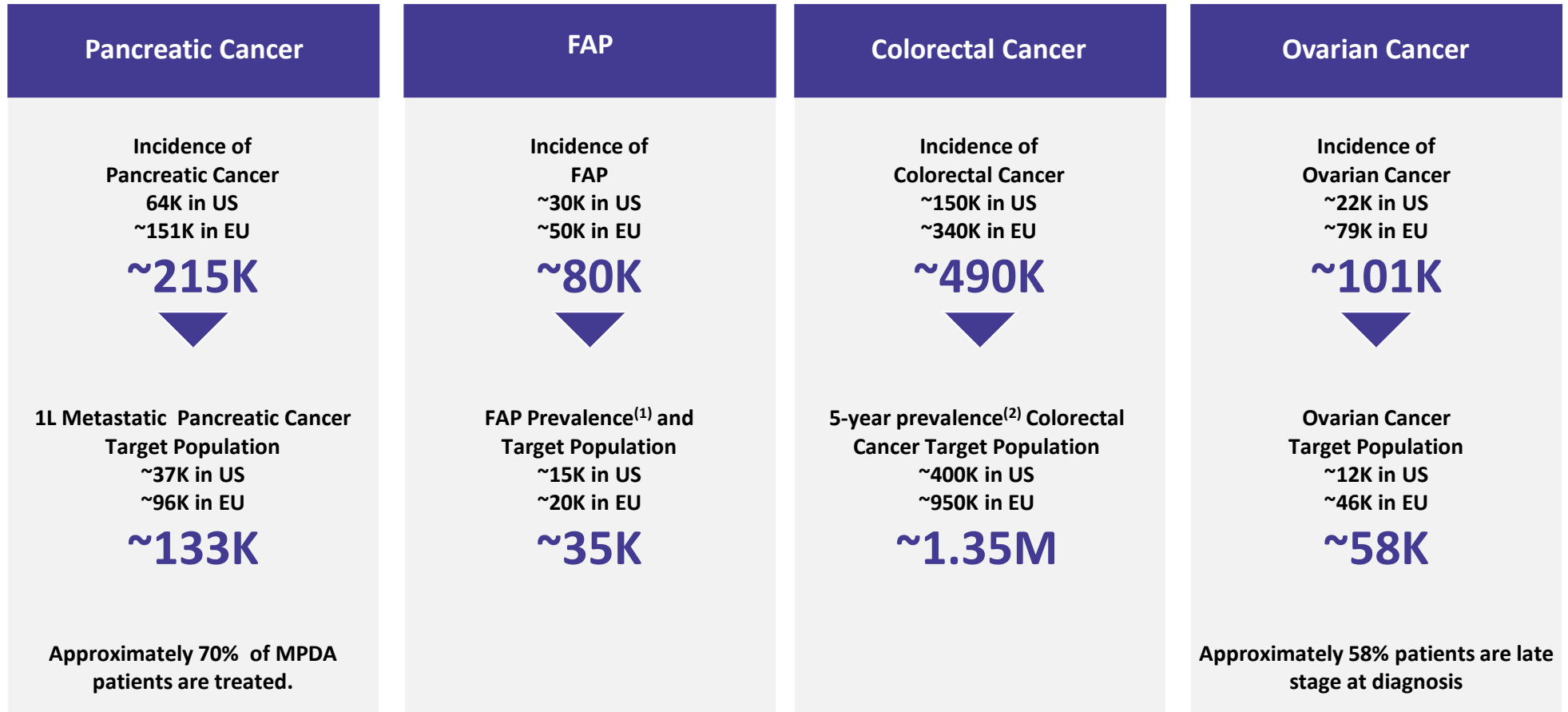
Initial focus on oncology and autoimmune disease - enhancing anti-tumor activity, preventing tumor growth, and modulating the immune system

<http://ibeliveit.ca/Personalized-Cancer-Medicine/Funding-byCancer-Typr.aspx>  
<https://www.benaroyaresearch.org/blog/post/mystery-multiple-autoimmune-diseases>  
 NSCLC- Non Small Cell Lung Cancer  
 \*Neuroblastoma program divested to USWM received FDA approval of NDA 12/2023

# Pipeline May Address Multiple Unmet Needs

	Preclinical	IND Ready	Phase I	Phase II	Phase III	Milestones
<b>SBP-101</b> (ivospemin) (Injection)	PDA (First Line Metastatic)					➤ Phase III Enrolling; Interim Analysis Mid 2024
	PDA Neoadjuvant					➤ Phase II Ready – Open 1H 2024
	Ovarian					➤ Phase I Ready – Open 1H 2024
<b>Flynpovi</b> (eflornithine/ sulindac combination tablet)	Familial Adenomatous Polyposis (FAP)					➤ Global Harmonization of Registration Protocol by 2H 2024
	Colon Cancer Risk Reduction (NCI Fund via Partnership with SWOG)					➤ Positive Futility Analysis – 1H 2023
<b>CPP-1X-S</b> Immunotherapy Enhancement (eflornithine sachets)	NSCLC (STK11 Mut) with Keytruda					➤ Phase I NSCLC Open FPI – 1H 2024
	Immunotherapy-nonresponsive Cancers					➤ Phase II NSCLC FPI – 1H 2024
<b>CPP-1X-T</b> (eflornithine 250 mg tablets)	Early Onset Type 1 Diabetes					➤ T1D Phase II Enrolling
	Prostate Cancer					➤ Prostate Phase II Enrolling
	Neuroblastoma – Divested to USWM					➤ Divested Neuroblastoma program- FDA approval of NDA 12/2023

# Potential \$5B Market Opportunity for Lead Programs



FAP Source: Burt et al 2010; Varesco et al 2004; multiple KOL sources.

Pancreatic Cancer Source: American Cancer Society. Cancer Facts & Figures 2023. Atlanta, GA: American Cancer Society; 2023 and Overview of Pancreatic Cancer Epidemiology in Europe and Recommendations for Screening in High-Risk Populations, Partyka, et al July 2023.

Colorectal Cancer Source: NCI Seer statistics 2018 and <https://ecis.jrc.ec.europa.eu>,

[https://seer.cancer.gov/csr/1975\\_2018/browse\\_csr.php?sectionSEL=1&pageSEL=sect\\_01\\_table.21](https://seer.cancer.gov/csr/1975_2018/browse_csr.php?sectionSEL=1&pageSEL=sect_01_table.21) and GLOBOCAN 2020.

Ovarian Cancer Source: American Cancer Society. Cancer Facts & Figures 2021. Atlanta, GA: American Cancer Society; 2021 and European Cancer Information Systems data 2020 (<https://ecis.jrc.ec.europa.eu/>).

1) Based on 1/10,000 prevalence, excludes 5% with no APC mut. Includes ages 15-74 and only patients with intact colon or retained rectum (~70% of FAP patients).

2) Prevalence is for "1st invasive tumor ever".

# Complementary Pharmacotherapies Targeting Dysregulation

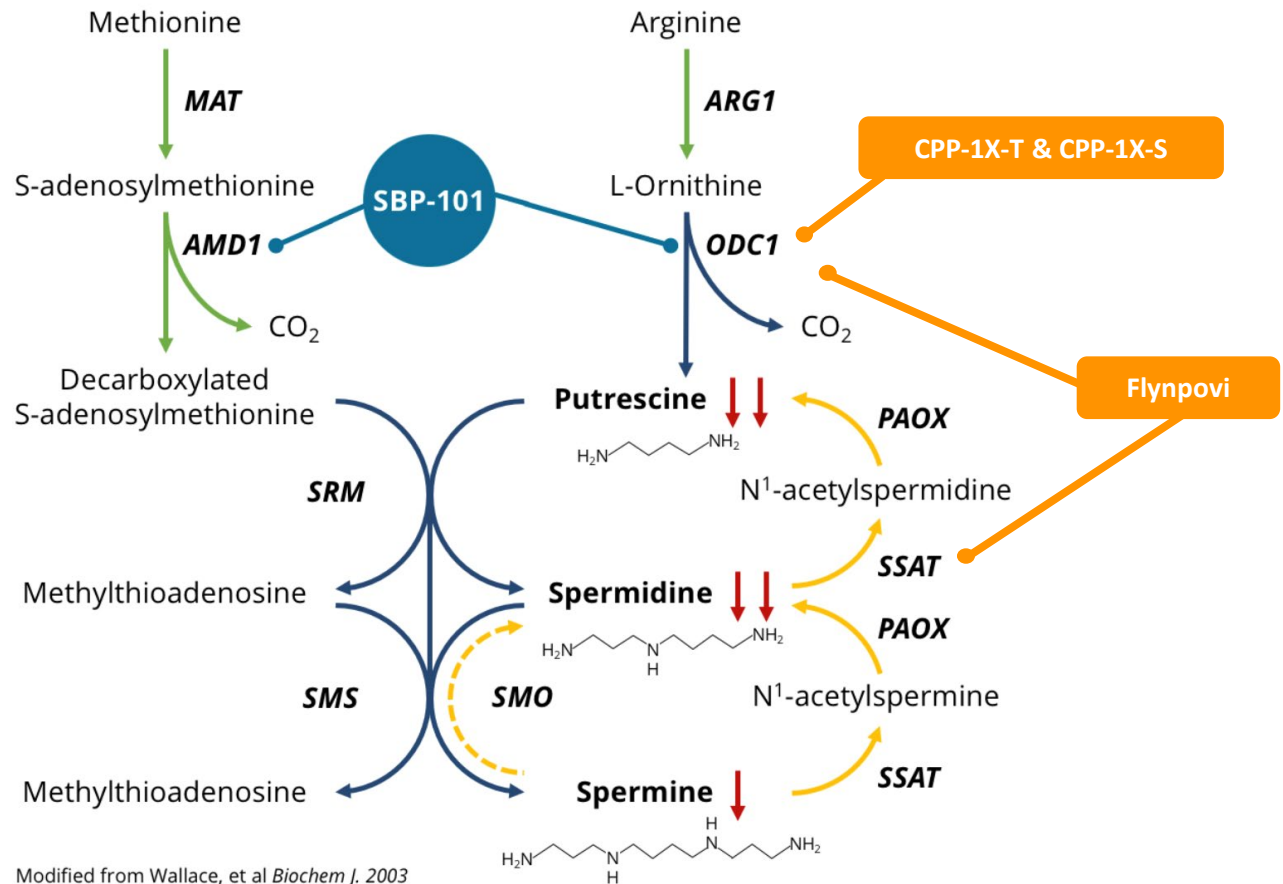
## Pipeline Objective

The objective of Panbela's pipeline is the utilization of pharmacotherapies to reduce/normalize increased disease-associated polyamines using complementary pharmacotherapies

## Current Pipeline

- 1 Ivospemin (SBP-101)
- 2 Flynpovi
- 3 CPP-1X-T
- 4 CPP-1X-S

## Combined pipeline pharmacotherapies hit different targets in the polyamine pathway







# Ivospemin (SBP-101)

# Preliminary Efficacy of ivospemin (SBP-101) + Gemcitabine/Nab-paclitaxel in First-Line Metastatic Pancreatic Ductal Adenocarcinoma

	BEST OVERALL RESPONSE				Overall Response	Disease Control
	CR	PR	SD	PD		
<b>ivospemin (0.40 mg/kg) + G/A* (Ph Ia COHORT 4 + Ph Ib) n=29</b>	1 (3%)	13 (45%)	10 (34%)	5 (17%)	<b>14/29 (48%)</b>	<b>24/29 (83%)</b>
<b>Gemcitabine + Nab-paclitaxel (G/A*)** n=431</b>	<1%	23%	27%	20%	<b>23%</b>	<b>48%</b>

	PFS		OS	
	Ph Ia 4+Ph Ib	G+A*	Ph Ia 4+Ph Ib	G+A*
<b>ivospemin (0.40 mg/kg) + G/A Cohort</b>				
<b>Median (mo)</b>	<b>6.5</b>	5.5	<b>14.6***</b>	8.5
<b>6 mo (%)</b>	<b>54</b>	44	<b>86</b>	67
<b>12 mo (%)</b>	<b>18</b>	16	<b>55</b>	35

\*G/A = gemcitabine + Nab-paclitaxel

\*\*Historical control data, MPACT study G+A arm, N=431 - Source: Von Hoff NEJM 2013

\*\*\* Final Data-3/18/22

PhIa = Phase Ia

PhIb = Phase Ib

CR-Complete Response; PR-Partial Response; SD-Stable Disease

Disease Control Rate = CR+PR+SD for > 16 weeks

# Efficacy Comparison of ivospemin (SBP-101) + Gemcitabine/Nab-paclitaxel vs. Standard of Care

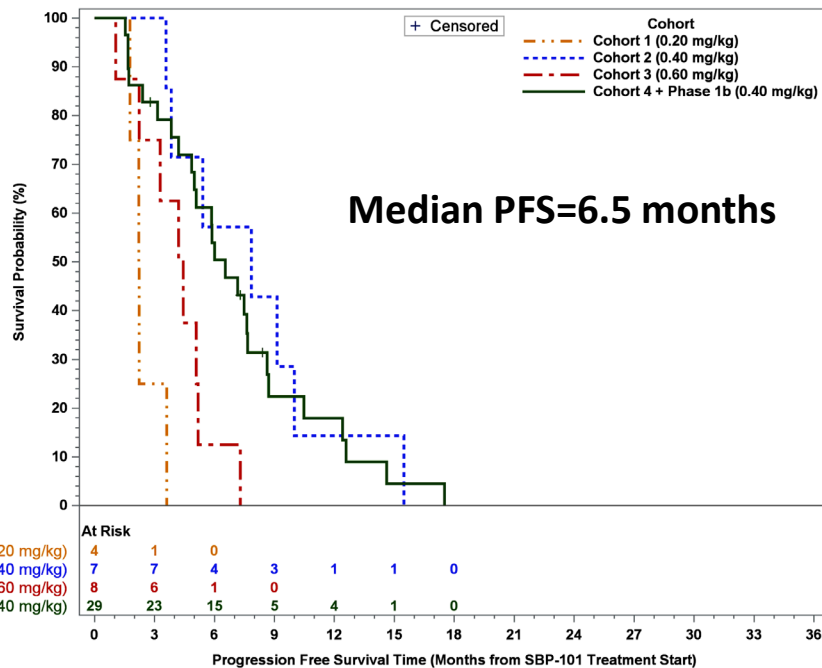
Treatment	OS	PFS	ORR	DCR	PD
CL-SBP-101-03 <sup>1</sup>	14.6 months	6.5 months	48.3%	82.8%	4.8%
FOLFIRINOX <sup>2</sup>	11.1 months	6.4 months	31.6%	70.2%	15.2%
Modified FOLFIRINOX <sup>3</sup>	10.2 months	6.1 months	35.1%	86.5%	13.5%
NALIRIFOX - Phase I/II (NAPOLI 3) <sup>4</sup>	12.6 months	9.2 months	34.4%	71.9 %	9.4%
NALIRIFOX - Phase III (NAPOLI 3) <sup>5</sup>	11.1 months	7.4 months	41.8%	67.6%	22.5%
Gemcitabine + Abraxane – Phase I/II <sup>6</sup>	12.2 months	7.9 months	48%	68%	16%
Gemcitabine + Abraxane (MPACT) <sup>7</sup>	8.5 months	5.5 months	23%	48%	20%
Gemcitabine + Abraxane-Phase III (NAPOLI 3) <sup>4</sup>	9.2 months	5.6 months	36.2%	62.3%	23.3%

1. CL-SBP-101-03 CSR (modified Efficacy Evaluable data n=29);
2. Conroy et al, 2011;
3. Stein et al, 2016 (MPC data);
4. Wainberg et al, 2021;
5. O'Reilly et al, 2023;
6. Von Hoff et al, 2011;
7. Von Hoff et al, 2013

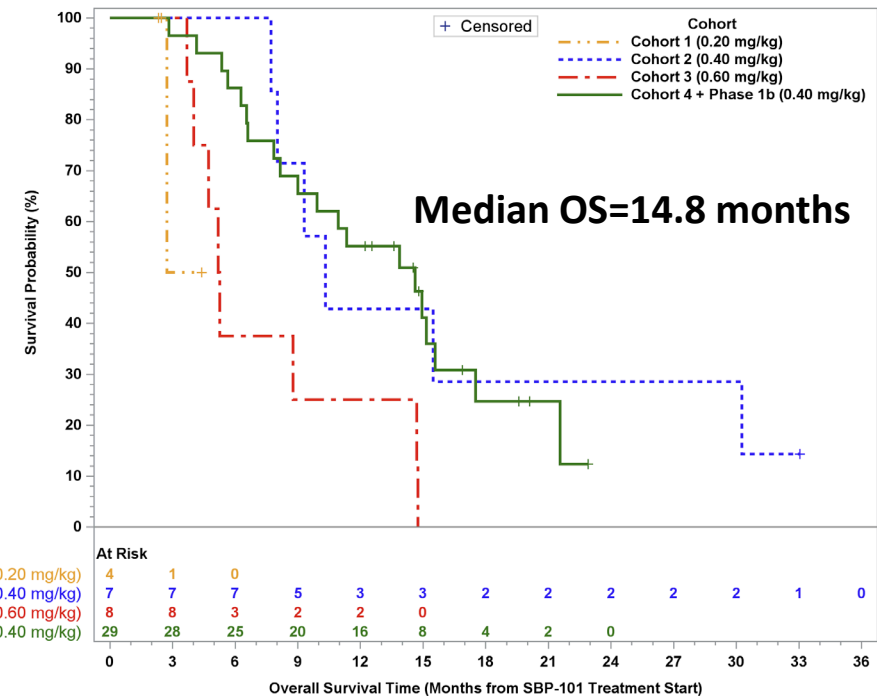
OS-Overall Survival  
PFS-Progression Free Survival  
ORR – Overall Response Rate  
DCR-Disease Control Rate  
PD – Progressive Disease

# Phase I Trial Efficacy of SBP-101 +Gemcitabine/Nab-paclitaxel

## Progression-Free Survival (PFS)



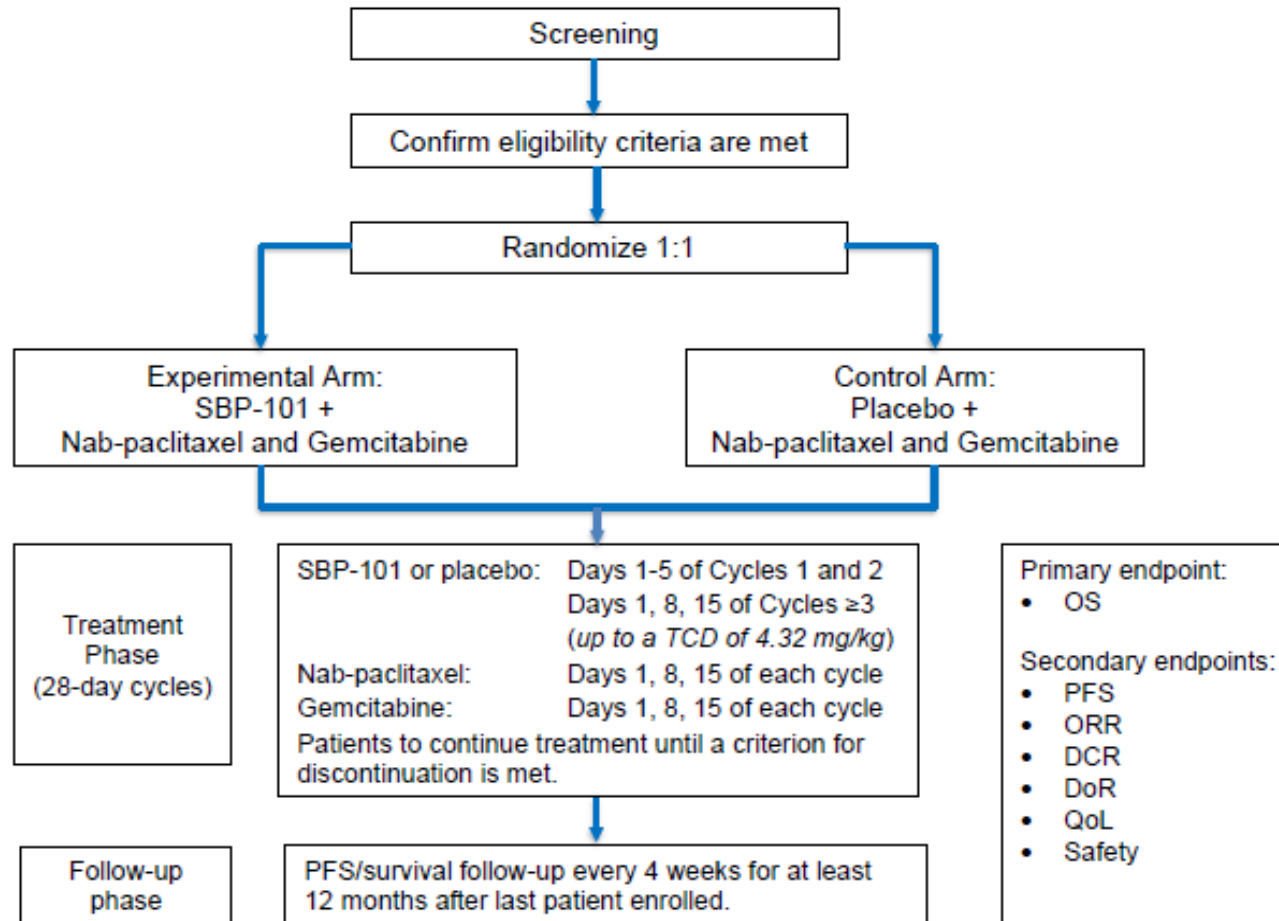
## Overall Survival (OS)



- Cumulative survival rates at 6 and 12 months were 86.2% and 55.2%. with 3 subjects (10.3%) alive at 19.6, 20.1, and 22.9 months.
- The cumulative PFS rates were 54.0% and 17.9% at 6 and 12 months.
- Nine (31%) subjects treated at the RD were alive at the time of data analysis and were censored for OS. These subjects were alive for an average of 16.4 months (range 12.2 – 22.9 months)

# Phase III Pancreatic Cancer Trial in Subjects Previously Untreated for Metastatic Pancreatic Ductal Adenocarcinoma

A Randomized, Double-Blind, Placebo Controlled Study of Nab-Paclitaxel and Gemcitabine with or Without ivospemin (SBP-101)



OS-Overall Survival  
PFS-Progression Free Survival  
ORR – Overall Response Rate  
DCR-Disease Control Rate  
DoR – Duration of Response  
QoL-Quality of Life

# Ivospemin (SBP-101) + Gemcitabine/Nab-paclitaxel Demonstrated a Similar Safety Profile to Gemcitabine/Nab-paclitaxel in First-Line Metastatic Pancreatic Ductal Adenocarcinoma

## Safety Results

Grade ≥3 AEs of Special Interest	N	SBP-101%		G+A %**
<b>Hematologic Events</b>				
Neutropenia	20	40%		38%
Leukopenia	0	-		31%
Anemia	9	18%		13%
Thrombocytopenia	1	2%		17%
Febrile Neutropenia	1	2%		3%
<b>Non-hematologic Events</b>				
Diarrhea	7	14%		6%
Fatigue	6	12%		17%
Peripheral Neuropathy	3	6%		17%

Grade ≥3 adverse events attributable to any study medication, N=50.				
Event	SBP-101	G+A**	All 3	Total N (%)
Neutropenia	0	19 (1G, 18 G+A)	1	20 (40%)
Elevated LFTs	5	0	9	14 (28%)
Anemia	0	7 (G+A)	0	9 (18%)
Diarrhea	0	6 (4A, 2G+A)	1	7 (14%)
Fatigue	0	4 (G+A)	2	6 (12%)
Vision events	4	1 (G)	2	7(14%)
Dehydration	2	2 (1A, 1 G+A)	0	4 (8%)
Peripheral neuropathy	0	3 (A)	0	3 (6%)

\*Historical control data, MPACT study, G+A arm, N= 431 - Source: Von Hoff 2013

\*\* G/A = gemcitabine + Nab-paclitaxel



**FLYNPOVI:  
A Combination of  
CPP-1X and Sulindac**

# Flynpovi – A Combination of CPP-1X and Sulindac for the Treatment of Familial Adenomatous Polyposis (FAP)

## Familial Adenomatous Polyposis (FAP)

- A genetic disease caused by APC mutations where colon polyps develop early in life
- Nearly 100% of patients will develop colon cancer if the polyps are left untreated

## Prevalence

**1-in-10,000**

**~30K in US**

**~50K in EU**

**Global Markets Opportunity**

## Key Information:

- No approved FAP drugs on the market
- Target Physicians: Gastroenterologists
- US-only potential revenue at market share of 35%-60% (approximately 11,300-18,400 potential patients)

## Pricing:

Annual Price	US only Potential Annual Revenue
\$20,000	\$227M - \$368M
\$25,000	\$284M - \$460M
\$30,000	\$341M - \$552M
\$35,000	\$397M - \$644M

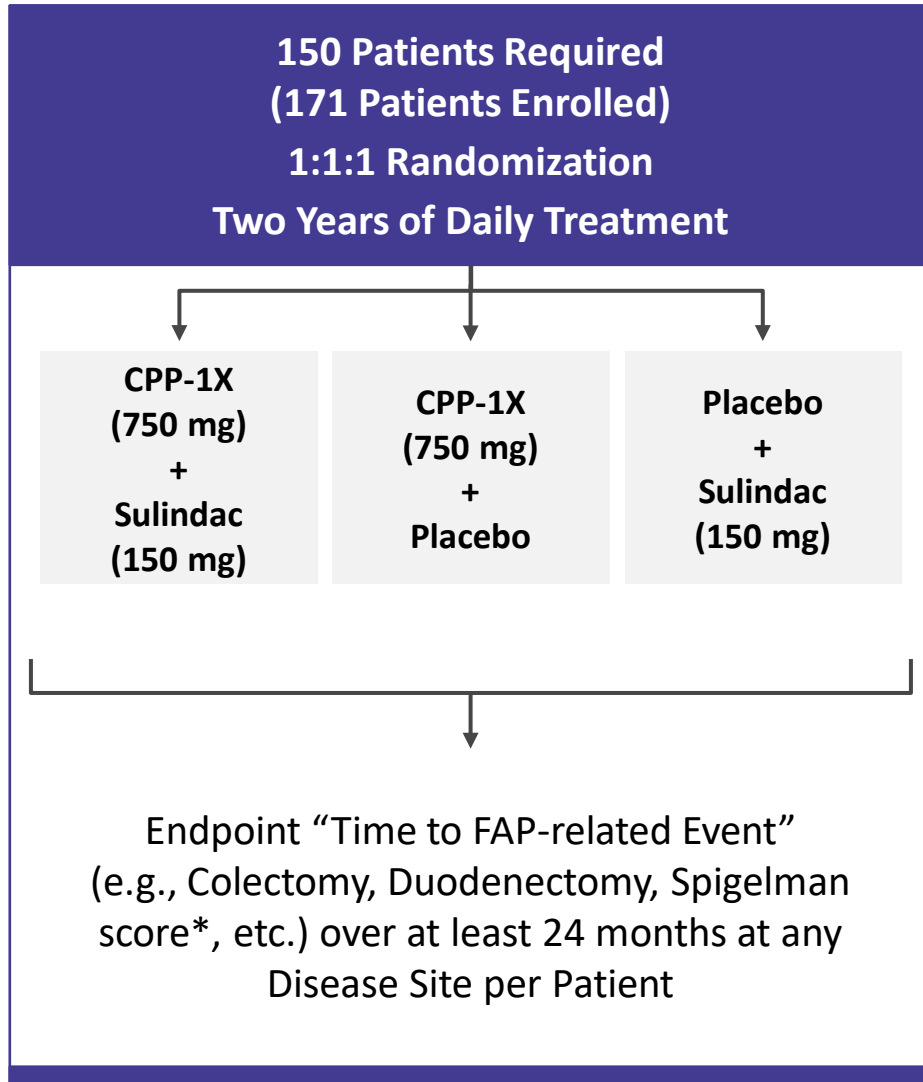
## Market:

- FAP affects all ethnicities
- In addition to the US - Significant market opportunity in Europe, China and Japan



# FAP-310 Trial: “Time to Delay FAP-related Event” Endpoint

## CPP FAP 310 global study



### Time to delay FAP-related events

Composite Endpoint including surgeries, polyp removal, and upper GI scoring system (“Spigelman”)\*; based on FDA/EMA recommendation-first ever “event” trial in FAP

### Surgical endpoints most meaningful

$p$  value with all elements of composite endpoint = 0.28 (i.e., with unvalidated non-surgery scoring system\* included)

$p = <0.02$  in delaying surgical and interventional events in “lower GI”

\* Determined to not be a “clinically meaningful” metric resulting in a change in the clinical management or treatment for the patient

# No Lower GI Surgeries for Flynpovi Combination

## Event Rate Distribution of FAP-Related Surgery Events in Lower GI

Surgery Events	ES Combo	Eflornithine	Sulindac	Overall
	(N=56)	(N=57)	(N=58)	(N=171)
Need colectomy	0	3	4	7
Need proctectomy	0	1	1	2
Need pouch resection	0	4	1	5
<b>Total Surgical Events</b>	<b>0</b>	<b>8</b>	<b>6</b>	<b>14</b>
<b>Event Rate</b>	<b>0/56 (0%)</b>	<b>8/57 (14%)</b>	<b>6/58 (10%)</b>	<b>14/171 (8%)</b>

**No surgeries** in Lower GI in ES Combo arm

## Adverse Events of Special Interest

Adverse Events of Special Interest	Flynpovi (Eflornithine + Sulindac Combination) N=56 Subjects (%)	Sulindac N=57 Subjects (%)	Eflornithine N=56 Subjects (%)
Anemia	1 (1.8)	5 (8.8)	2 (3.6)
Myelosuppression	0	1 (1.8)	0
Thrombocytopenia	0	3 (5.3)	1 (1.8)
Cardiovascular/Thrombotic events	1 (1.8)	1 (1.8)	1 (1.8)
Hearing impairment/Tinnitus	5 (8.9)	8 (14.0)	2 (3.6)
Non-bleeding GI event	33 (58.9)	25 (43.9)	28 (50.0)
Bleeding GI event	17 (30.4)	17 (29.8)	10 (17.9)
Headache/Migraine/Tension Headache	8 (14.3)	13 (22.8)	7 (12.5)
Dizziness/Vertigo	4 (7.1)	4 (7.0)	7 (12.5)

- **Comparable safety** amongst all treatment arms

# Summary of Approach to Approval

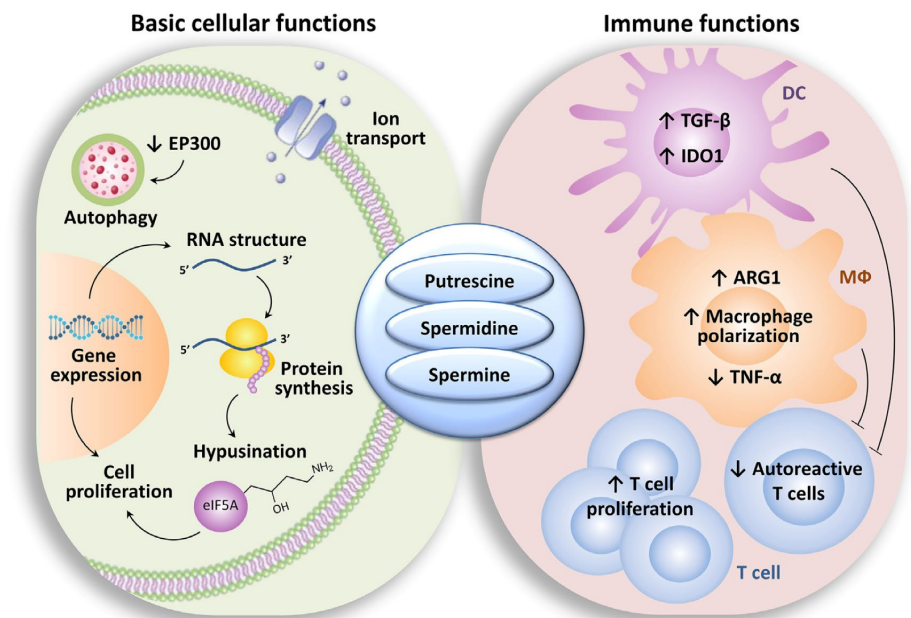
## Strong Results in the Lower GI

- ✓ Focus on Lower GI: statistically significant p-values and hazard ratios for clinically meaningful surgical endpoints—emphasized by regulators—in Phase III pivotal trial
- ✓ Expected safety profile over 2-4 years of daily dosing in Phase III pivotal trial
- ✓ Totality of the evidence includes mechanistic, preclinical, and clinical supportive data
- ✓ Seek approval of global registration trial design from FDA and EMA

**No Other Approved Therapy for this Orphan Disease**

# Role of Polyamines in Immune Dysregulation

- Immune systems require multiple soluble and cellular components, including polyamines, for a normal immune function
- High levels of polyamines are present in tumor cells and in autoreactive B- and T-cells in autoimmune diseases
- Dysregulation of polyamines can result in:
  - Tumor immune evasion
  - Elevated cell stress
  - Increased autoimmunity
- Panbela's pipeline focuses on **resetting the polyamine pathway to restore normal immune function**



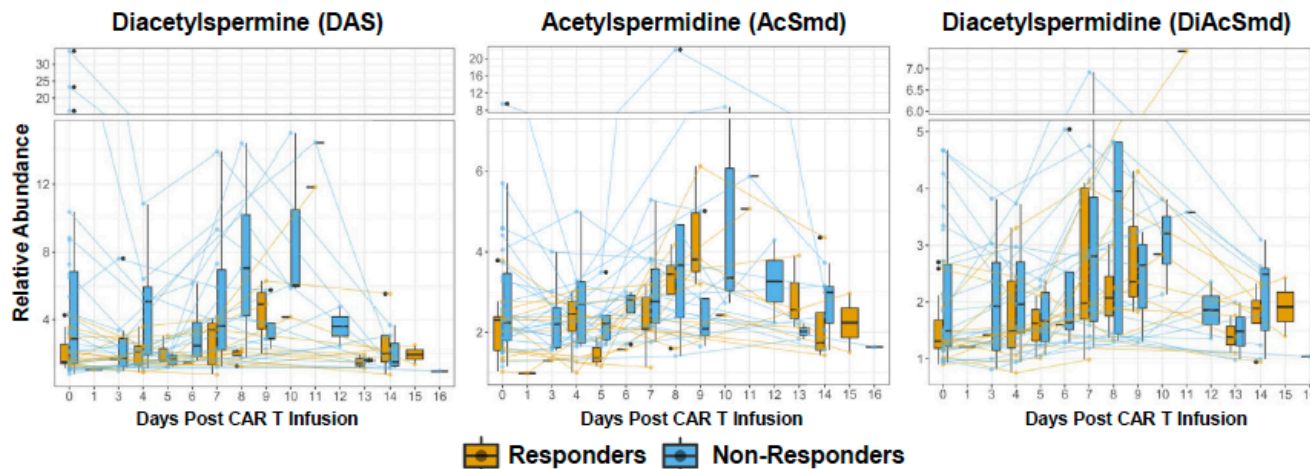
Proietti E et al 2020 Trends in Immunol



# Polyamines & Immune Dysregulation

# Potential Role of Polyamines in Diffuse Large B Cell Lymphoma (DLBCL) CAR-T Therapy

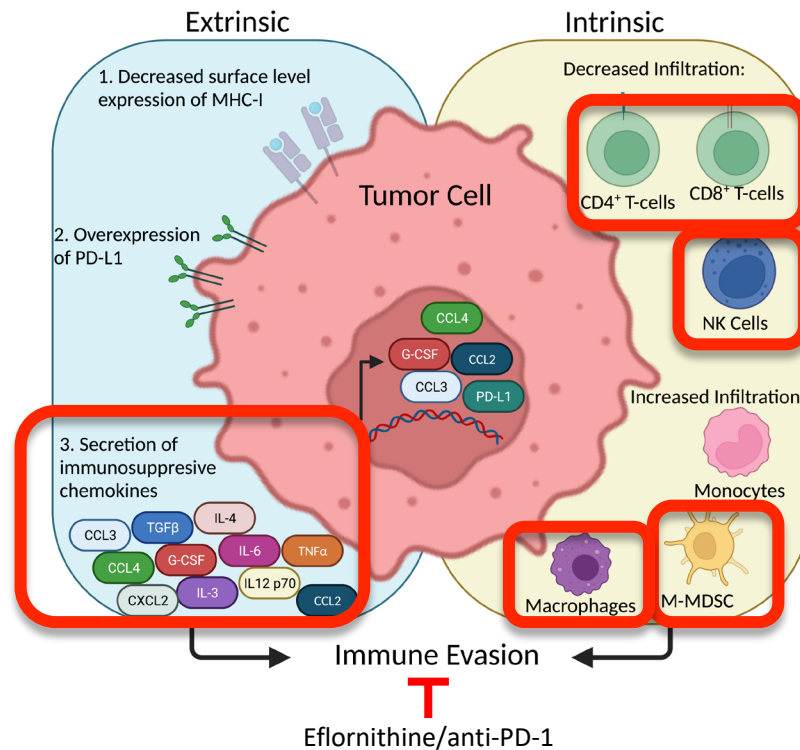
- Polyamine metabolism upregulation through oncogenic MYC is a common metabolic irregularity in aggressive cancers, including lymphomas.
- MYC overexpression in relapsed/refractory DLBCL prior to CAR-T cell therapy negatively associated with durable response to CAR-T cell therapy.
- Circulating acetylated polyamine levels may function as a predictor of therapeutic outcome to CAR-T cell therapy.
- This suggests a possible strategy to target polyamine metabolism to augment the efficacy of CAR-T cell therapy.



Intra-patient slopes considering random variables for intercept and slope			
Metabolite	Responders	Non-Responders	Pval
DAS	-0.077 (-0.107 to -0.065)	0.086 (0.062 to 0.115)	<0.0001
AcSpmid	0.028 (0.013 to 0.048)	0.074 (0.057 to 0.087)	<0.0001
DiAcSpmid	0.034 (0.020 to 0.034)	0.069 (0.057 to 0.078)	<0.0001

# Rationale for Eflornithine/anti-PD-1 Combination

- Targeting Ornithine decarboxylase (ODC) using eflornithine unmasks antitumor T cell immune response by weakening of tumor-induced immune suppression that is mediated by Myeloid-Derived Tumor Suppressor Cells (MDSCs).
- The addition of anti-PD-1 prevents the functional exhaustion of these surviving T cells leading to enhanced antitumor effects.
- The combination of eflornithine/anti-PD1 prevents immune evasion
- **Targeting the polyamine pathway, treatment may reinvigorate the T cell-directed activity of an anti-PD-1 therapy and promote immune-mediated elimination of tumor cells.**







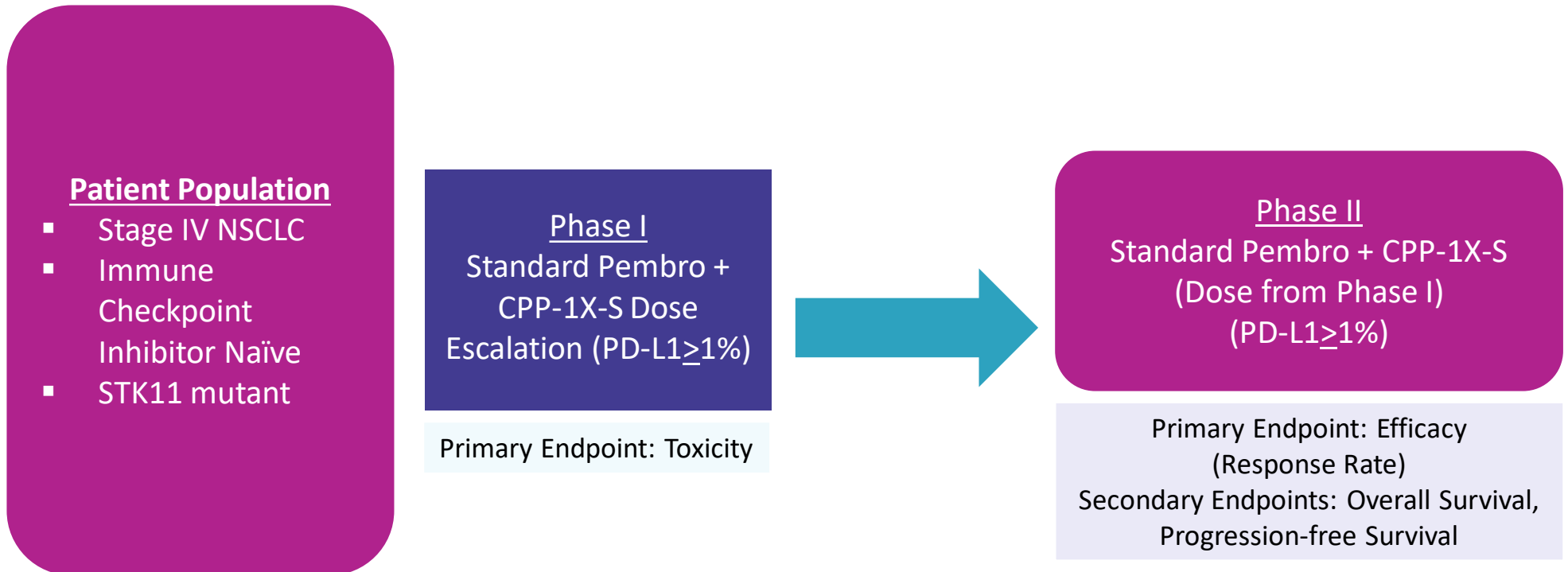
# CPP-1X-S

# Rationale for CPP-1X-S (Eflornithine Sachets) in STK11 Mutant NSCLC

- In preclinical tumor models, eflornithine treatment improves anti-PD-1 efficacy by:
  - Increasing tumor-specific cytotoxic T-cell populations
  - Increasing expression of PD-1 on tumor-associated CD8+ T cells
- ~10% of NSCLC cancers have STK11 mutations
- STK11 mutant NSCLC tumors have:
  - Reduced cytotoxic T-cells infiltrates
  - Upregulation of the arginine pathway which utilizes ODC to increase levels of the polyamine putrescine
  - Respond poorly to immune checkpoint inhibitor therapy

# STK11 Mutant NSCLC Investigator-Initiated Trial

*Collaborating with investigators at Moffitt Cancer Center on Phase I/II trial: “**Targeting Ornithine Decarboxylase as an Immunotherapeutic Target in STK11 (LKB1) Pathway-Deficient Non-Small Cell Lung Cancer**”*



First Clinical Proof of Concept for Polyamine Modulation of the Immune System



# **USWorld Medicines Neuroblastoma Program**

## Anticipated Milestones from USWM Neuroblastoma Program

FDA granted approval to eflornithine (IWILFIN) as a treatment for adult and pediatric patients with high-risk neuroblastoma (HRNB) who have achieved a partial response or better to a previous, multiagent, multimodal treatment including an anti-GD2 immunotherapy

- First polyamine targeted therapy approved in oncology

### Milestones:

- Up to \$9.1M in milestone payments related to clinical development, regulatory approval and commercial sales.



# Business Overview

# Barriers to Entry – Flynpovi/CPP-1X

- ▶ **Orphan status (7 years exclusivity US; 10 years exclusivity EU) for CPP-1X**
  - Granted in US and EU for FAP
  - Granted in US for Gastric cancer and Pancreatic cancer
- ▶ **Pharmaceutical Composition Patent**
  - Fixed dose combination eflornithine + sulindac
  - Broadly nationalized with potential protection through 2037
- ▶ **Method of Use Patents/Patent Applications**
  - Fixed dose combination of eflornithine + sulindac and eflornithine single agent
  - “Theranostic” patents will afford protection to 2034 (“theranostic”= drug + diagnostic to guide therapy)
  - Use for Treating FAP with potential protection through 2040
  - Use in Treating Recent Onset Type 1 Diabetes with potential protection through 2041
  - New patents under consideration

## Barriers to Entry – ivospemin (SBP-101)

- ▶ **Orphan status (7 for years exclusivity US; 10 years exclusivity EU) for SPB-101**
  - Granted in US and EU for pancreatic cancer
- ▶ **METHODS FOR PRODUCING (6S,15S)-3,8,13,18-TETRAAZAICOSANE-6,15-DIOL**
  - PCT application filed January 29, 2019
  - Granted in United States, United States (CON), India, Japan, Australia, Europe, China
  - Pending in Canada
  - 20-year expiration date is January 29, 2039
- ▶ **DOSING REGIMENS AND METHODS FOR TREATING CANCER**
  - PCT application filed January 20, 2021
  - Pending in United States, Australia, Canada, Japan, Europe, and Hong Kong
  - 20-year expiration date is January 20, 2041
- ▶ **COMBINATION TREATMENT FOR OVARIAN CANCER**
  - PCT application filed June 21, 2023



# Summary of Milestones

## 1H 2024

- Open- Neoadjuvant Pancreatic Cancer Trial
- FPI NSCLC Phase 1 Trial
- Open Phase 1 Ovarian Trial
- Gastric Cancer Prevention Phase II Results
- **Publication of Final Phase 1 Metastatic Pancreatic Trial Data**
- **Overall Survival Interim Analysis Phase III ASPIRE Trial**

## 2H 2024

- **Overall Survival Interim Analysis Phase III ASPIRE Trial**
- Obtain feedback from FDA and EMA for Global Registration Program in FAP
- Open NSCLC Phase II Trial

FPI-First Patient In  
FAP-Familial Adenomatous Polyposis  
NSCLC – Non Small Cell Lung Cancer

## Financial Position - Cash and Debt (unaudited)

Cash and Debt	
Cash at 9/30/2023	907
Net cash from warrant inducement on 11/2/2023 & 12/21/2023	3,687
Net cash from voluntary warrant exercise	1,223
Proforma net cash as of 9/30/2023 <sup>1</sup>	5,817
Debt at 9/30/2023	
Current (due 1/31/2024)	1,000,000
Non-current	<u>4,194,000</u>
Total	5,194,000

(1) Proforma Cash consists of 9/30/23 balance plus disclosed equity transactions subsequent to 9/30/23. Does not reflect any undisclosed Cash used in Operations.

## Capital Stock (unaudited)

### Panbela

Common Stock issued and outstanding at 9/30/2023	2,996,334
Shares issued in for exercise of warrants after 9/30/2023	6,609,406
Other activity after 9/30/2023	2,345
<b>Total Proforma Common stock outstanding</b>	<b>9,608,085</b>
Shares reserved for Options (WAE = \$1,071.08) at 9/30/2023	13,455
Shares reserved for Warrants (WAE = \$10.28) at 9/30/2023	4,068,826
Warrants exercised after 9/30/2023	(6,620,728)
Warrants issued after 9/30/2023	9,372,000
<b>Total Proforma Outstanding and Reserved</b>	<b>16,441,638</b>

## Summary:

### Unique Scientific Approach: Resetting dysregulation via polyamine pathway



Broad, late-stage de-risked pipeline opportunities



Multiple partnerships supporting development programs



Significant market potential



Multiple data readouts expected



Experienced management team