



Investor Presentation

October 2023

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2023

Disclaimers

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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.

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

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

2

- Late-stage programs are orphan oncology related: pancreatic cancer and FAP (familial adenomatous polyposis)

3

- Combined pipeline spans from pre-clinical to Phase III registration programs

4

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

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

13+ Years



Rachel Bragg
VP, Clinical Development

14+ Years

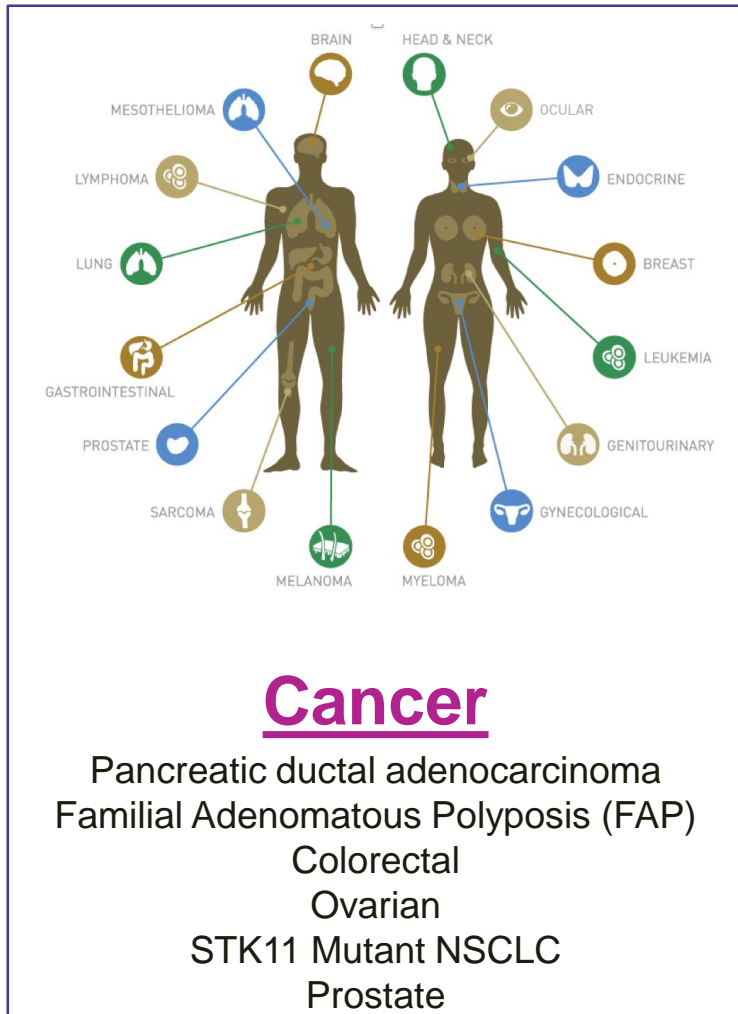


Dr. Ashok Chavan
VP, CMC, QA, Supply Chain

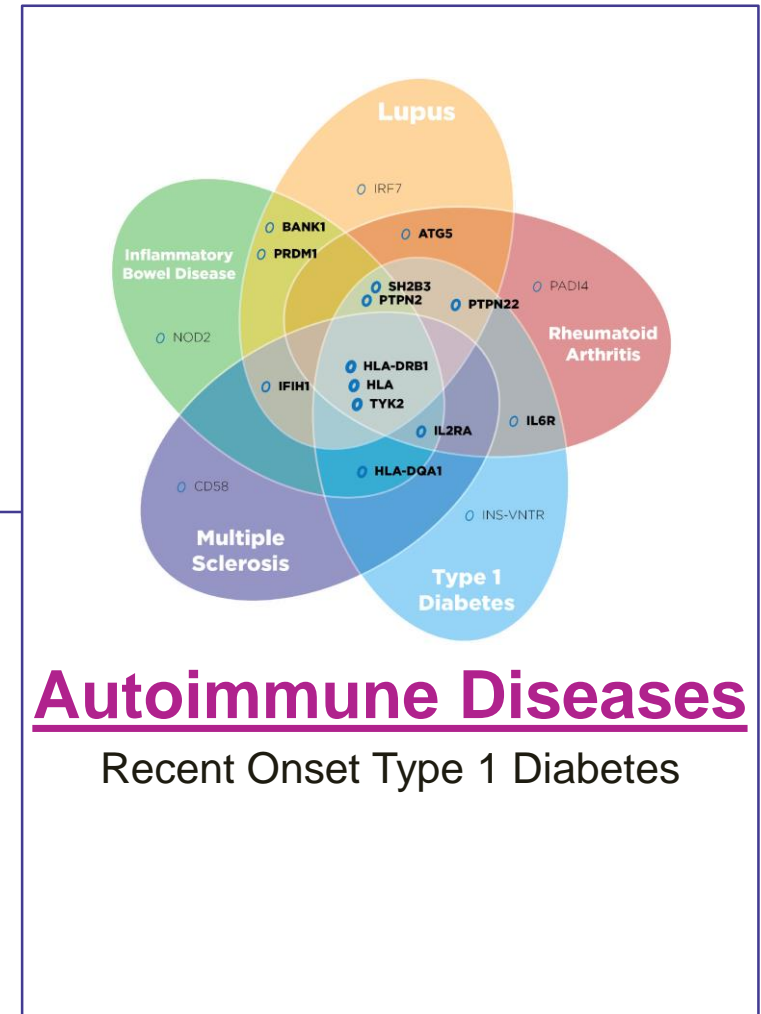
15+ Years

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

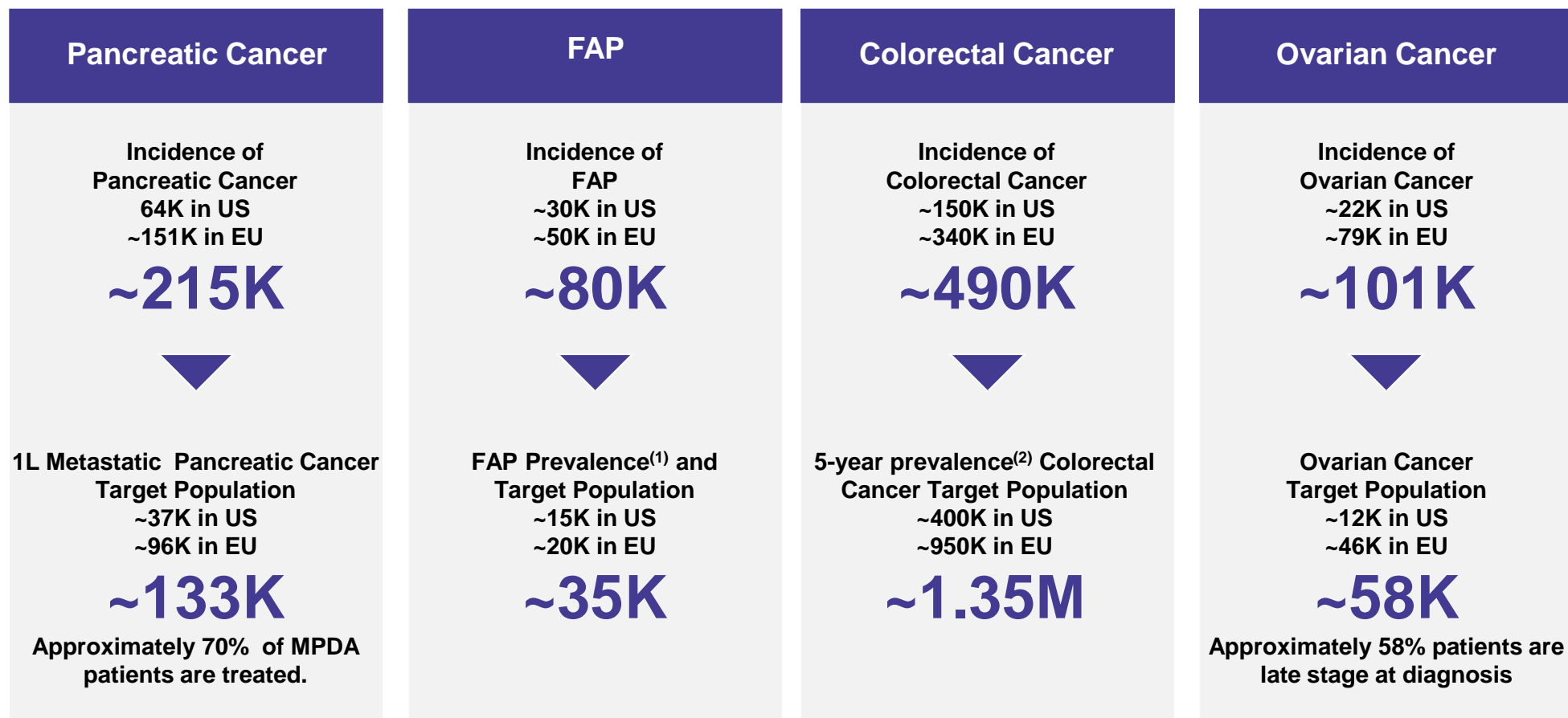


Initial focus on oncology and autoimmune disease - enhancing anti-tumor activity, preventing tumor growth, and modulating the immune system

Pipeline May Address Multiple Unmet Needs

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

Potential 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 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

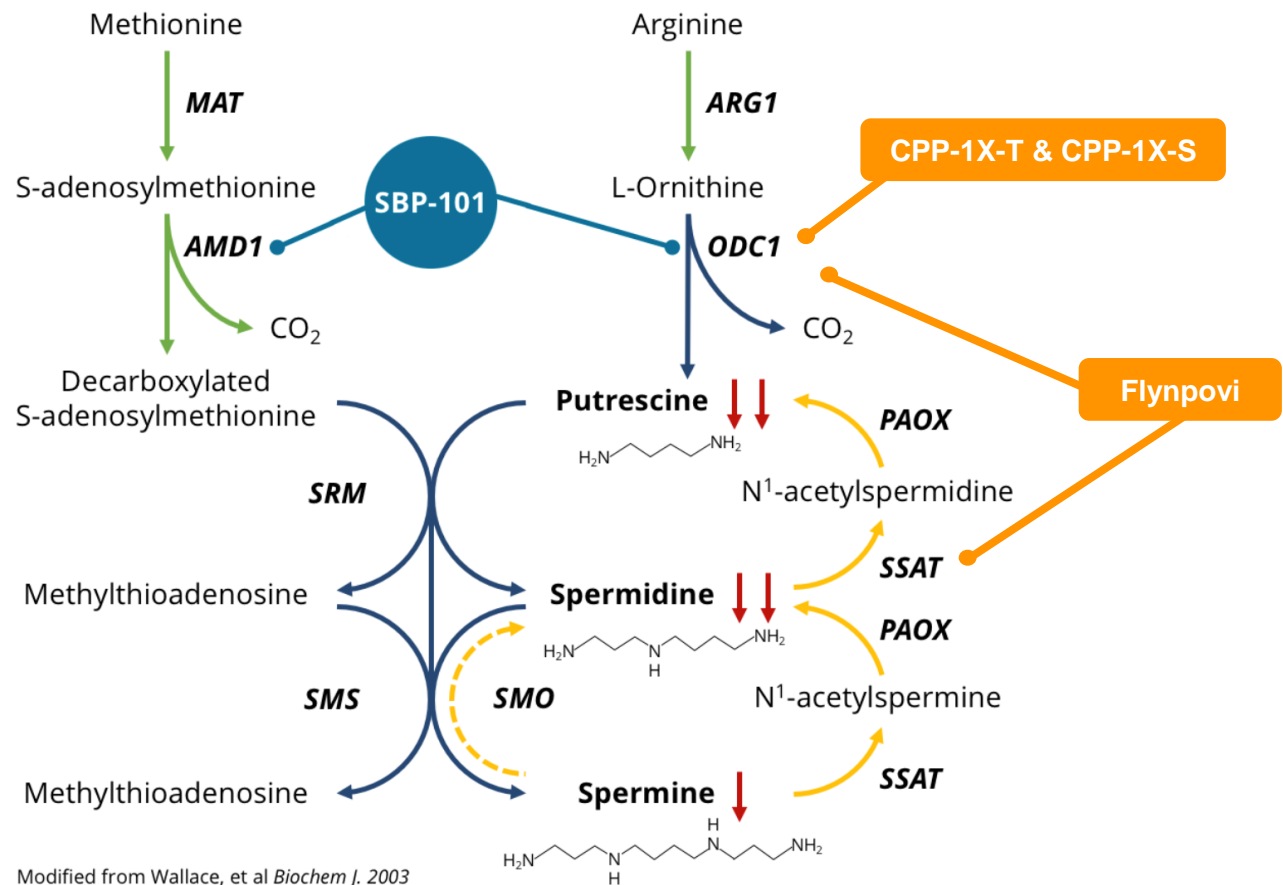
Pipeline Objective

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		
Ivospemin (0.40 mg/kg) + G/A* (Ph Ia COHORT 2) n=7	0	5 (71%)	2 (29%)	0	5/7 (71%)	5/7 (71%)
ivospemin (0.40 mg/kg) + G/A* (Ph Ia COHORT 4 + Ph Ib) n=29	1 (3%)	13 (45%)	10 (34%)	5 (17%)	14/29 (48%)	24/29 (83%)
Gemcitabine + Nab-paclitaxel (G/A*)** n=431	<1%	23%	27%	20%	23%	48%

	PFS			OS		
	Ph1a 2	Ph Ia 4+Ph Ib	G+A*	Ph Ia 2	Ph Ia 4+Ph Ib	G+A*
ivospemin (0.40 mg/kg) + G/A Cohort						
Median (mo)	5.6	6.5	5.5	10.3	14.6***	8.5
6 mo (%)	43	54	44	100	86	67
12 mo (%)	0	18	16	43	55	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

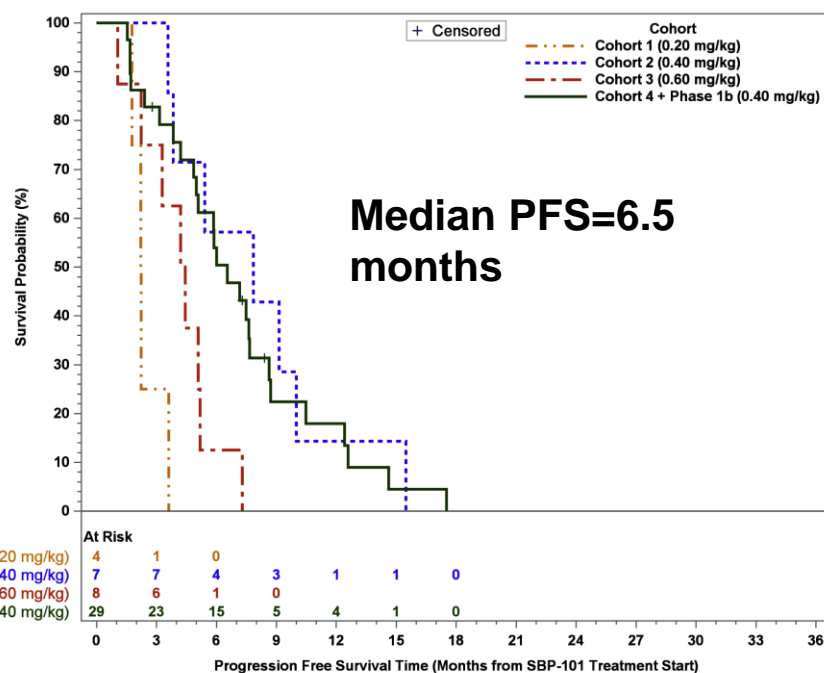
Treatment	OS	PFS	ORR	DCR	PD
CL-SBP-101-03 ¹	14.6 months	6.5 months	48.3%	82.8%	4.8%
FOLFIRINOX ²	11.1 months	6.4 months	31.6%	70.2%	15.2%
Modified FOLFIRINOX ³	10.2 months	6.1 months	35.1%	86.5%	13.5%
NALIRIFOX - Phase I/II (NAPOLI 3) ⁴	12.6 months	9.2 months	34.4%	71.9 %	9.4%
NALIRIFOX - Phase III (NAPOLI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

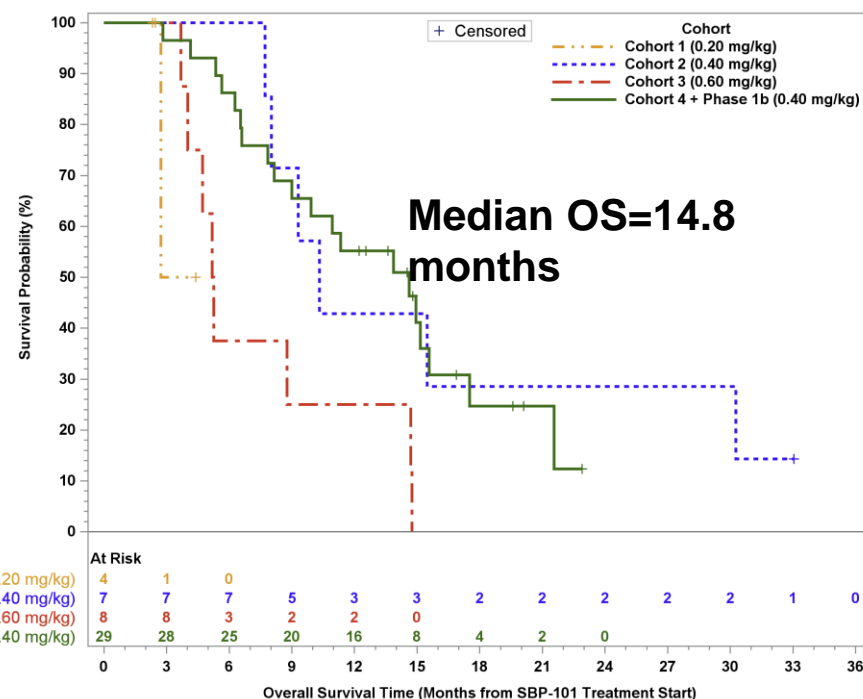
OS-Overall Survival
PFS-Progression Free Survival
ORR – Overall Response Rate
DCR-Disease Control Rate
PD – Progressive Disease

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)

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 %**
Hematologic Events				
Neutropenia	20	40%		38%
Leukopenia	0	-		31%
Anemia	9	18%		13%
Thrombocytopenia	1	2%		17%
Febrile Neutropenia	1	2%		3%
Non-hematologic Events				
Diarrhea	7	14%		6%
Fatigue	6	12%		17%
Peripheral Neuropathy	3	6%		17%

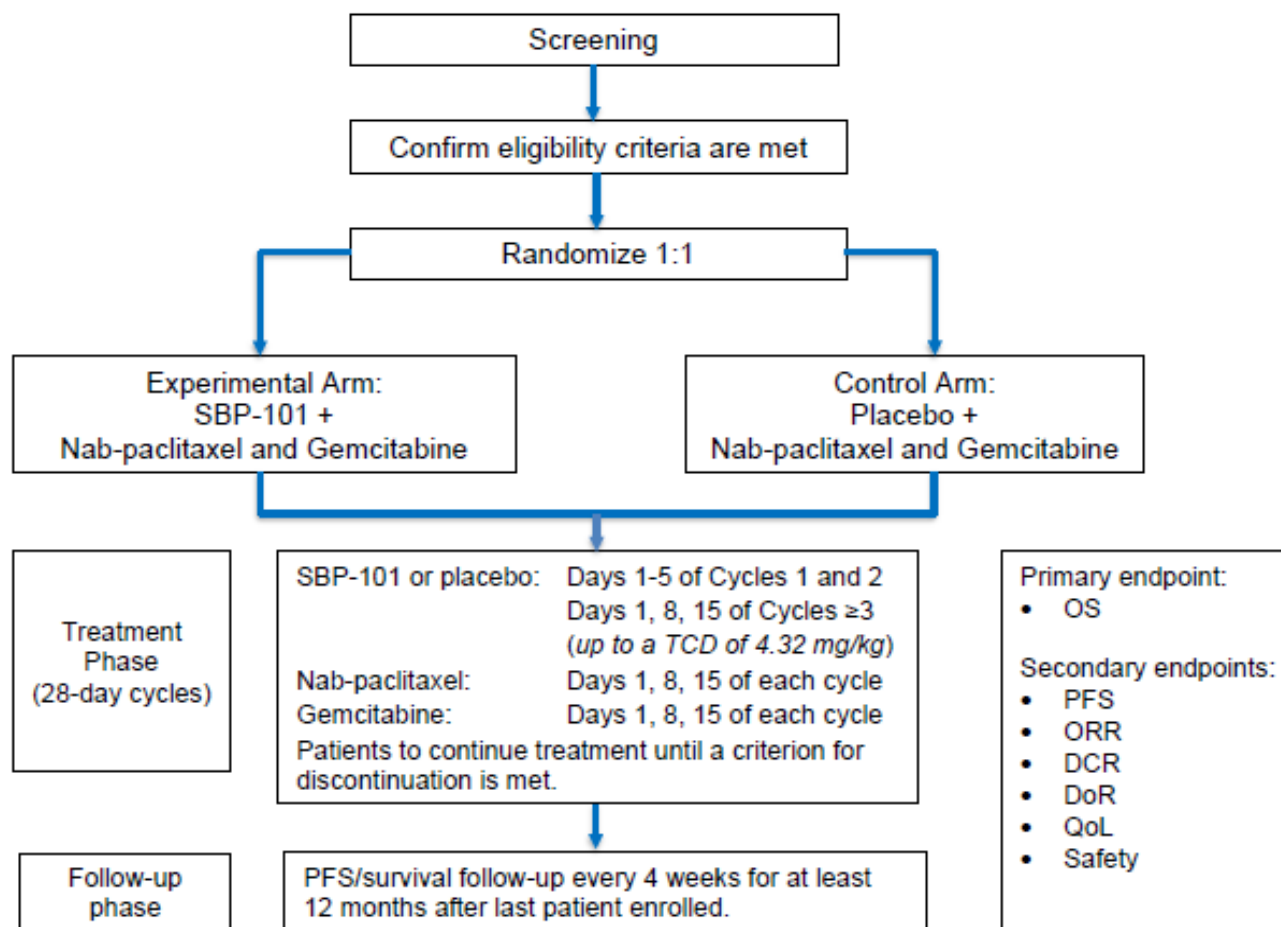
Grade ≥3 adverse events attributable to any study medication, N=50.				
Event	SBP-101	G+A**	All 3	Total N (%)
Neutropenia	0	19 (1G, 18 G+A)	1	20 (40%)
Elevated LFTs	5	0	9	14 (28%)
Anemia	0	7 (G+A)	0	9 (18%)
Diarrhea	0	6 (4A, 2G+A)	1	7 (14%)
Fatigue	0	4 (G+A)	2	6 (12%)
Vision events	4	1 (G)	2	7 (14%)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

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 ivosipemin (SBP-101)





FLYNPOVI: A Combination of CPP-1X and Sulindac

Lead Product Opportunity – CPP-1X and Sulindac (Flynpovi)

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:

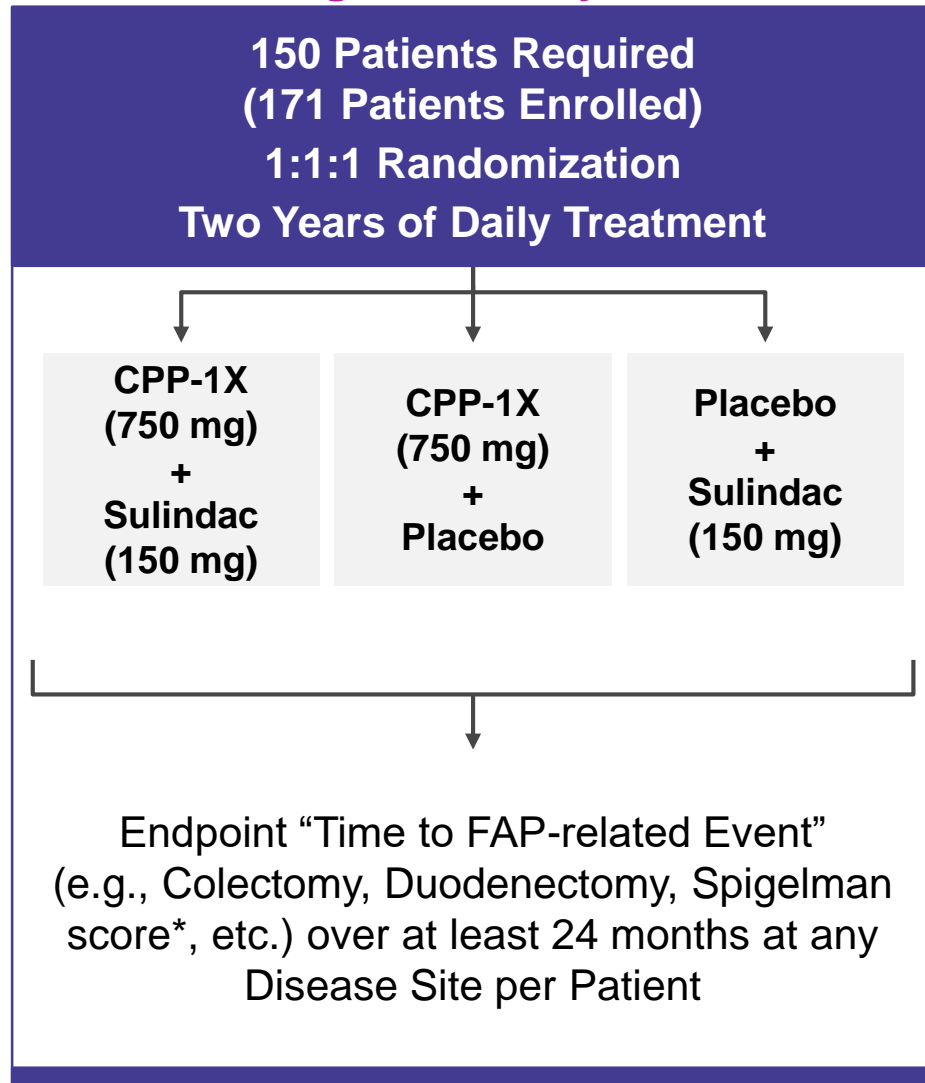
Annual Price	US only Potential Annual Revenue
\$20,000	\$227M - \$368M
\$25,000	\$284M - \$460M
\$30,000	\$341M - \$552M
\$35,000	\$397M - \$644M

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

Burke et al 2020 NEJM

Balaguer et al 2022 DCR

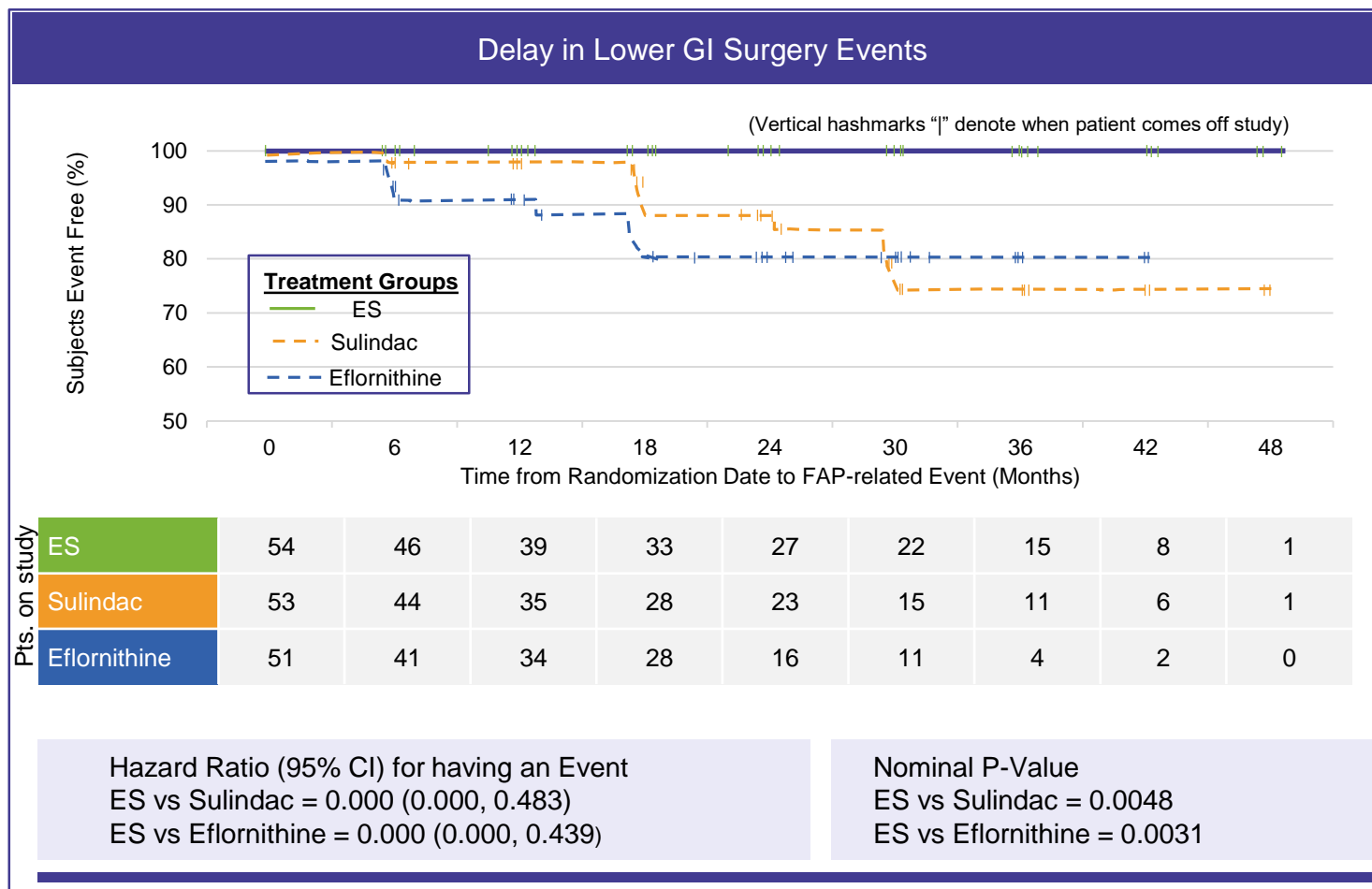
No Lower GI Surgeries for Flynpovi Combination

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
Total Surgical Events	0	8	6	14
Event Rate	0/56 (0%)	8/57 (14%)	6/58 (10%)	14/171 (8%)

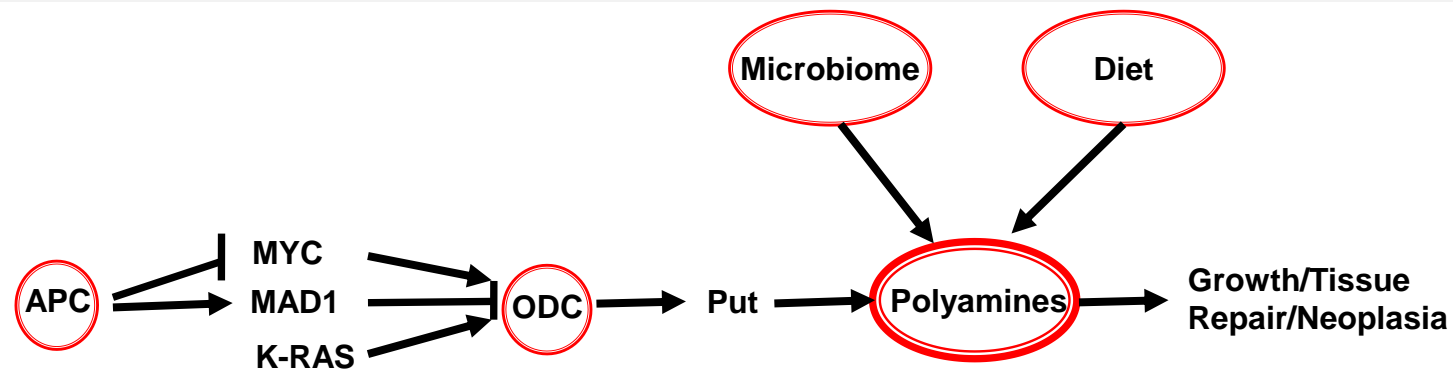
No surgeries in Lower GI in ES Combo arm

Flynpovi Combination Delays Need for Lower GI Surgery

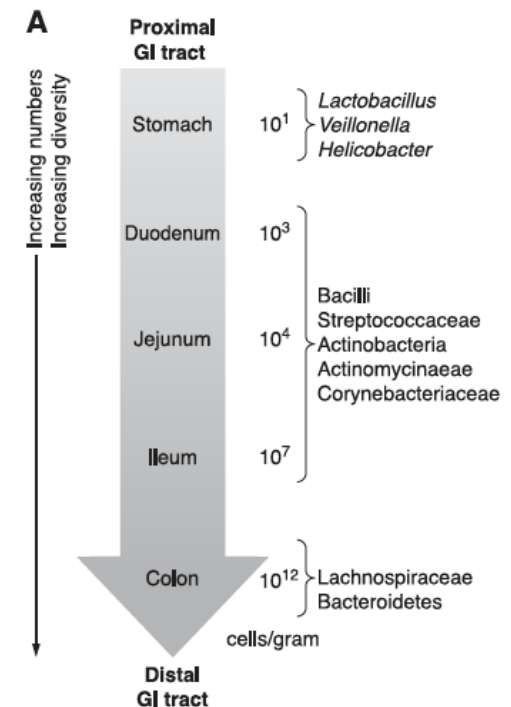


In Subjects with Lower GI Anatomy (i.e., excludes 13 patients with ileostomy)

Rationale for Efficacy of Flynpovi in the Lower Gastrointestinal Tract of FAP Patients



- ▶ Polyamines can be synthesized but also derived from the diet and microbiome.
- ▶ The microbiota increases steadily along the gastrointestinal tract.
 - Small numbers in the stomach but very high concentrations in the colon.
 - Areas of the LGI contain up to nine orders of magnitude (10^9) more bacteria than that in the duodenum and other areas of the UGI.
 - Colonic mucosa of FAP patients can harbour biofilms containing tumorigenic bacteria
- ▶ **Contribution of the microbiota in addition to APC driving ODC provides a potential mechanism of action for the enhanced efficacy of Flynpovi in the LGI via polyamines.**



Johnson et al 2015; Dejea et al 2018; Sekirov et al 2010

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

Basis for FDA Complete Response Letter

■ Clinical

- Single pivotal study efficacy was based on exploratory post-hoc analysis using a modified primary endpoint in a subgroup of the intent-to treat population
 - Asked to perform a new study focused on FAP patients with an intact lower-GI tract which showed statistically significant effect in post-hoc analysis of FAP-310 trial

■ Quality

- Proposed dissolution condition for testing of Eflornithine is different from the FDA Guidance for Industry: Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products
 - ✓ Revised dissolution specifications
- Limited discriminating ability of the dissolution method for compression force and no discriminating ability for the magnesium stearate or sulindac particle size distribution
 - Dissolution method being revised to address concerns

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

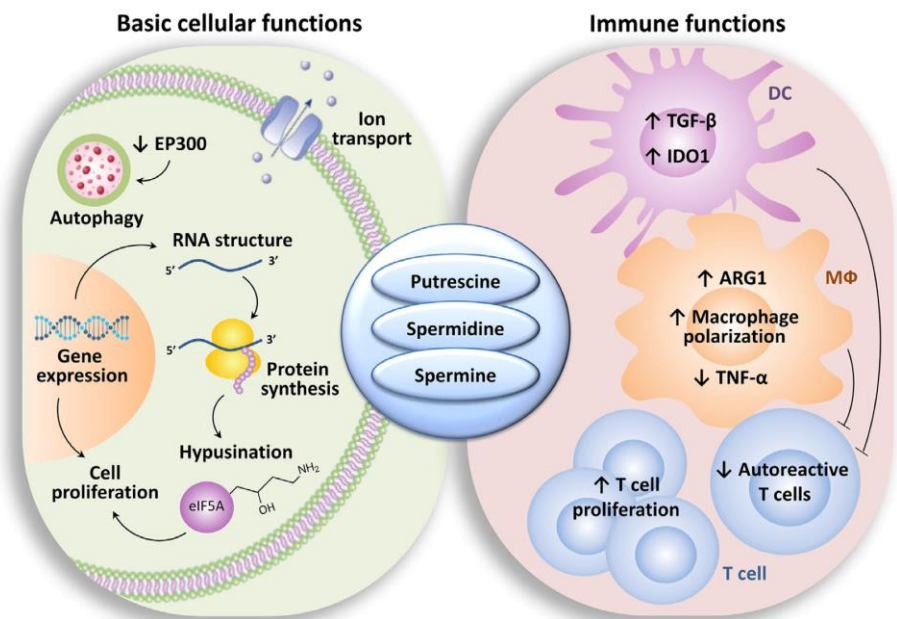
No Other Approved Therapy for this Orphan Disease



Polyamines & Immune Dysregulation

Role of Polyamines in Immune Dysregulation

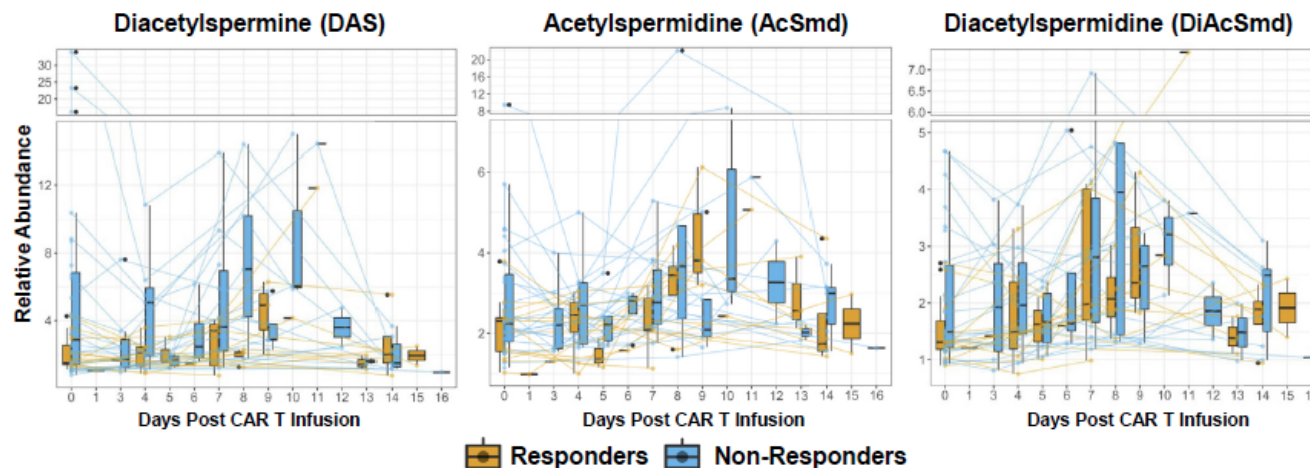
- Immune systems require multiple soluble and cellular components, including polyamines, for a normal immune function
- High levels of polyamines are present in tumor cells and in autoreactive B- and T-cells in autoimmune diseases
- Dysregulation of polyamines can result in:
 - Tumor immune evasion
 - 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

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

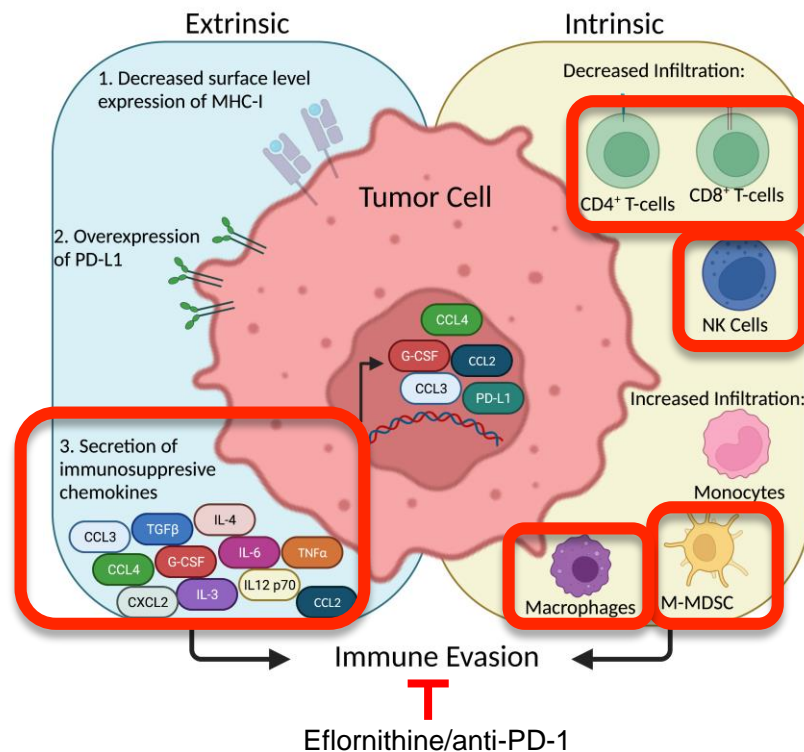
- Polyamine metabolism upregulation through oncogenic MYC is a common metabolic irregularity in aggressive cancers, including lymphomas.
- MYC overexpression in relapsed/refractory DLBCL prior to CAR-T cell therapy negatively associated with durable response to CAR-T cell therapy.
- Circulating acetylated 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
AcSmd	0.028 (0.013 to 0.048)	0.074 (0.057 to 0.087)	<0.0001
DiAcSmd	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**”*

Patient Population

- Stage IV NSCLC
- Immune Checkpoint Inhibitor Naïve
- STK11 mutant

Phase I

Standard Pembro +
CPP-1X-S Dose
Escalation (PD-
L1 \geq 1%)

Primary Endpoint:
Toxicity



Phase II

Standard Pembro + CPP-1X-
S (Dose from Phase I)
(PD-L1 \geq 1%)

Primary Endpoint: Efficacy
(Response Rate)
Secondary Endpoints: Overall
Survival, Progression-free Survival

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



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 2023

- ✓ Open- Phase I NSCLC Trial
 - Open- Neoadjuvant Pancreatic Cancer Trial
- ✓ Open – Phase II Type I onset Diabetes Trial
- ✓ Futility Analysis Phase III Colon Cancer Risk Reduction Trial (PACES)

2H 2023

- ✓ Prespecified Safety Analysis by DSMB for the Aspire Trial
 - **Publication of Phase I Type I early onset Diabetes Data**
 - **Publication of Final Phase I Metastatic Pancreatic Trial Data**
 - **Gastric Cancer Prevention Phase II Results**
- Obtain feedback from FDA and EMA for Global Registration Program in FAP
- Open Phase I Ovarian Cancer Trial
- Open Phase I NSCLC Data

1H 2024

- Open Phase II NSCLC Trial
- **Overall Survival Interim Analysis Phase III ASPIRE Trial**

ASCO-American Society of Clinical Oncology
GI-Gastrointestinal
mPC-Metastatic Pancreatic Cancer
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 6/30/2023	7,205,000
Debt at 6/30/2023	
Current (due 1/31/2024)	1,000,000
Non-current	<u>4,194,000</u>
Total	5,194,000

(1) Proforma Cash consists of 12/31/22 balance plus disclosed equity transactions subsequent to 12/31/22. Does not reflect any undisclosed Cash used in Operations.

Capital Stock (unaudited)

Panbela

Common Stock at 6/30/2023	2,612,038
Shares issued in exchange for warrants 7/1/2023 to 8/10/2023	84,744
Prefunded warrants exercised 7/1/2023 to 8/10/2023	<u>260,954</u>
Total Proforma Common stock outstanding	2,957,736
Shares reserved for Options (WAE = \$1,071.08) at 6/30/2023	13,455
Shares reserved for Warrants (WAE = \$9.91) at 8/10/2023	4,218,826
Total Proforma Outstanding and Reserved	7,190,017

(1) All Common stock, Option and Warrant amounts have been restated for 1 for 30 reverse stock split effected on 6/1/2023

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