Processa Pharmaceuticals, Inc. (NASDAQ: PCSA)

Update / August 11, 2022

Processa Pharmaceuticals

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Our People Lead to Success

Management Team

David Young, PharmD. PhD
President and Chief Executive Officer

Sian Bigora, PharmD.
Chief Development Officer

Michael Floyd
Chief Operating Officer

Patrick Lin
Chief Business – Strategy Officer

James Stanker, CPA
Chief Financial Officer

Wendy Guy
Chief Administrative Officer

Board of Directors

Justin Yorke
Chairman of the Board
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

David Young, PharmD. PhD
President and CEO, Processa Pharmaceuticals
Former CSO and Director, Questcor Pharmaceuticals

Khoso Baluch
Independent Director
Former CEO of CorMedix, Inc.
Independent Director, Poxel SA

James Neal
Independent Director
CEO and Chairman of the Board, XOMA Corp

Geraldine Pannu
Independent Director
Founding and Managing Partner of GLTJ Pioneer Capital

Virgil Thompson
Independent Director
Former Chairman of the Board, Questcor Pharmaceuticals

Processa Pharmaceuticals, Inc (NASDAQ: PCSA) Highlights

- **Development Company** Focused on **Improving the Quality of Life (QOL) and/or Survival of Patients** with an Unmet Medical Need Condition
- Management & Development Team with **Track Record of Success**
- **Regulatory Science Approach** to Drug Development Initially Developed during FDA Collaborations 30 Years Ago and Refined over Time with Approvals in Almost Every Division of FDA
- In-licensed Five Drugs Each with **Potential Sales of > $1.0B Plus Some Evidence of Efficacy** in the Targeted Population of Patients
- 4 of the 5 drugs have INDs, **3 of the 4 drugs are presently in clinical trials**, and the development strategy for 1 of the 4 drugs is being refined prior to putting it into a clinical study
- The **6422 clinical trial is now up and running with sites recruiting** as they were prior to the protocol changes (based on our interim analysis) resulted in regulatory delays at FDA and the sites
- Although enrollment in the **PCS499** studies has been slower than hoped, **our supplemental patient enrollment programs** (e.g., travel reimbursement, study-specific website) **have recently resulted in an increase in the number of patients inquiring about their eligibility** for screening in these trials
- **Patient enrollment for the PCS12852 gastroparesis trial has done very well** and we expect to complete the study by the end of the year

Processa's Risk Abated Approach and Criteria for Drug Selection

Experience in Adding Value to Companies: > 30 FDA Approvals & Regulatory Science Contracts from FDA

DEVELOP NOT **DISCOVER**

REGULATORY SCIENCE PLATFORM

Unmet Medical Need	+	Efficacy Evidence	+	Regulatory Science	+	Capital Efficiency	+	Potentially High ROI
• Clear and obvious **patient need** • **Favorable competitive** dynamics		• **Evidence of clinical efficacy** in targeted medical condition • **Higher** probability of **successful development**		• **Improve Benefit/Risk** profile that FDA evaluates for approval • **Optimize trial design** and **anticipate** what **FDA** requires for approval (Trifecta: decreasing risk, time to approval & cost)		• **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.) • **Efficient development** program and clinical trial design		• **Intelligently monetize and partner assets**

Pipeline of Five Drugs Each with $1B Market Opportunity

- 4 Drugs in Clinical Stage of Development and 1 in Pre-IND
  - 3 Drugs Targeting the Treatment of Cancer (Phase 1B, Phase 2B, Pre-IND Stage) (Blue Box, Blue Arrows)
  - 1 Drug in Phase 2B Targeting an Orphan Condition with no Approved Treatments and No Effective Standard of Care and 1 Drug in Phase 2A Targeting an Unmet Medical Need Condition Where the Existing Treatment Options have Limited Use with Serious Adverse Events (Orange Box, Yellow Arrow)

Drug	Disease Target	Non-clin	Phase 1	Phase 2	Phase 3
Next Generation Capecitabine Phase 1B (PCS6422)	Metastatic Colorectal, Other Cancers				
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica				
PCS12852 Phase 2A	Gastroparesis				
PCS3117 Phase 2B	Pancreatic, Other Cancers				
PCS11T Pre-IND	SC Lung, Other Cancers				

Pipeline Milestones During the Next 12 Months

Drug	Disease Target	Status and Milestones
Next Generation Capecitabine Phase 1B (PCS6422)	**Metastatic Colorectal, Other Cancers**	• Cohort 1 and 2A Completed, 1 Pt in Cohort 2B completed, 1 Site being Added (Total of 6 Sites) • Complete Enrollment and Interim Analysis of Cohort 2A, 2B, 2C to Better Understand the Timeline of Inhibition & De Novo Formation of the DPD Enzyme • Complete 1B Trial & Identify MTD • Finalize Potential Paths to Approval & Meet with FDA to Define Path Forward
PCS499 Phase 2B	**Ulcerative Necrobiosis Lipoidica**	• 3 Pts Completed Trial, Supplemental Patient Enrollment Programs are now having an Effect on Enrollment • Complete Interim Cohort Enrollment and Analysis of Primary Endpoint • Complete Trial Enrollment & Analysis, Finalize Potential Paths to FDA Approval, & Meet with FDA to Define Path Forward
PCS12852 Phase 2A	**Gastroparesis**	• Enrolled 20 out of 24 patients • Complete Enrollment & Obtain Final Results • Initiate Phase 2B Trial
PCS3117 Phase 2B	**Pancreatic, Other Cancers**	• Finalize Potential Paths to FDA Approval & Meet with FDA to Define Path Forward
PCS11T Pre-IND	**SC Lung, Other Cancers**	• Select Manufacturing Sites & Design Initial Clinical Program

Questions and Answers

- What is Management doing to deal with the progress of the programs, especially enrollment in 499 and 6422?
  - Has Processa considered that the eligibility requirements to enroll in their trials may be too stringent?
  - Is it possible that Processa is splitting resources across the drugs in the pipeline too much causing delays? Does the company need more resources?

- What is your plan for each asset?
  - Do you plan to partner or out-license each asset and, if you do, when?
  - How do you plan to fund the next studies?

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Pipeline Background Slides

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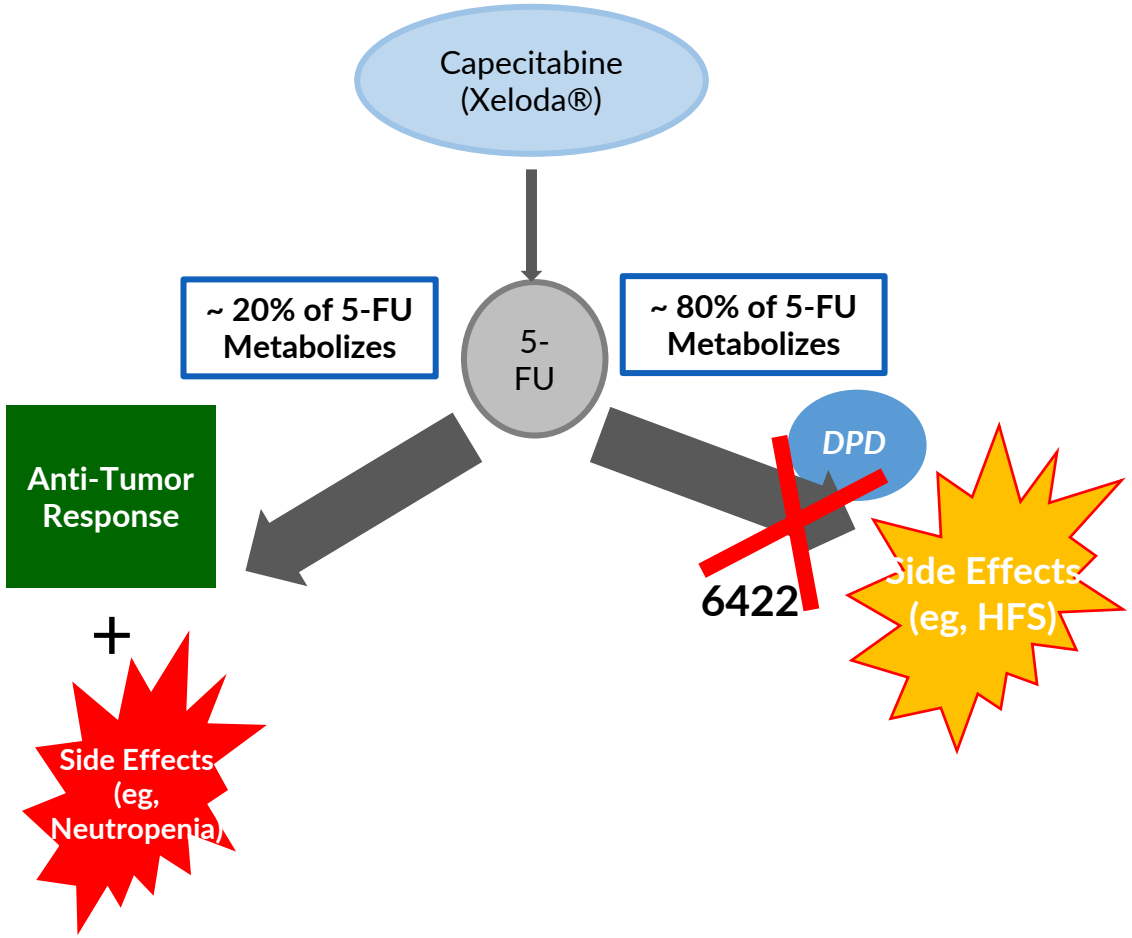
Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)

Metastatic Colorectal Cancer, Breast Cancer, Pancreatic Cancer, Other Cancers

Next Generation Capecitabine Improves Safety/Efficacy Profile of Capecitabine (Combination of PCS6422 and Capecitabine)

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



6422 Inhibits DPD Allowing Two Ways to Win

- **Lower Side Effects** by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- **Improve Capecitabine Efficacy** – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

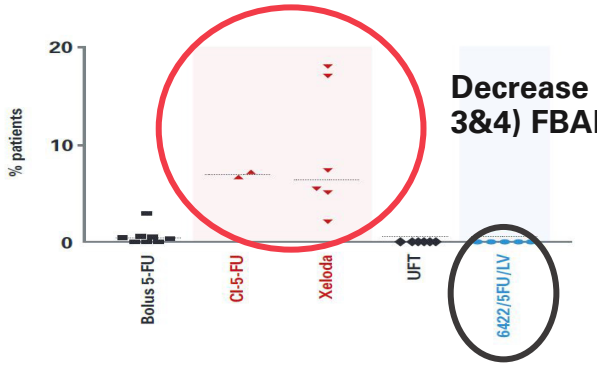
Economic Value: Initial Markets

- Potential for Next Generation Capecitabine to replace capecitabine in the treatment of colorectal cancer and other cancers
- Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total colorectal cancer patients worldwide; > 45% of the new patients with colorectal cancer presently receive capecitabine
- U.S. market potential in colorectal cancer is ~ $1.0 B

Unmet Medical Need and Evidence of Clinical Benefit

➢ Safety Differentiation of 6422+Capecitabine vs Existing Chemotherapy

- 50-70% of capecitabine patients have adverse events from FBAL resulting in decreasing capecitabine dose or stopping therapy
- Clinical trial of the 6422 + capecitabine provides preliminary evidence that the combination will decrease FBAL adverse events



Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects

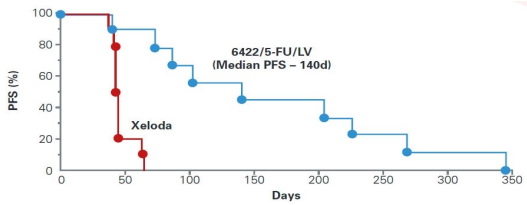
Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2017. NEJM

➢ Efficacy Differentiation of 6422+Capecitabine vs Existing Cancer Chemotherapy

- ~30% of patients do not respond at all to capecitabine and ~30% are partial responders
- Clinical trial of the 6422 + capecitabine combination provides preliminary evidence that the combination may extend progression free survival (PFS) in patients who do not respond to capecitabine as well as increase PFS in those patients who do respond

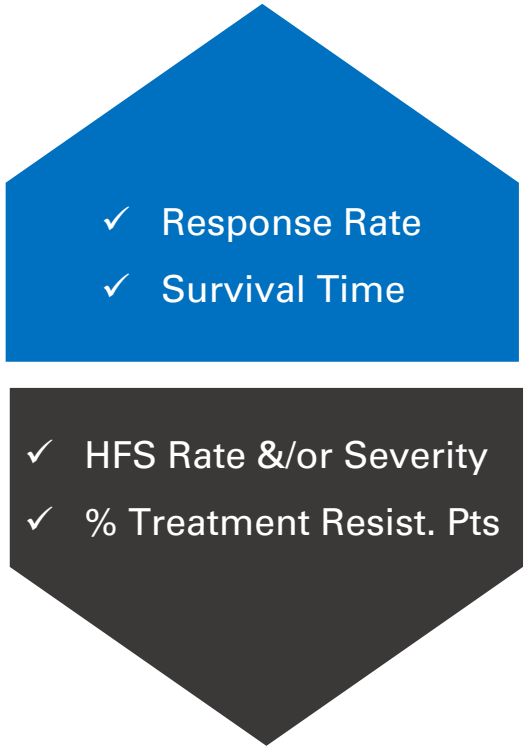
Improve Capecitabine Efficacy with 6422:

Lower Dose of 6422 Administered Hours Before 5-FU/LV in Capecitabine Resistant Patients



5-FU = 5-Fluoruracil; LV = Leucovorin; PFS = Progression Free Survival, SD = Stable Disease; PR = Partial Response; PD = Progressive Disease

Next Generation Capecitabine (Combination of PCS6422 and Capecitabine)



Phase 1B Next Generation Capecitabine Cohort 1 and 2 Interim Results

- No DLTs, no drug-related adverse events greater than Grade 1, and no hand-foot syndrome side effects were observed in Cohort 1 and 2
- Next Generation Capecitabine with 1 dose of 6422 inhibited DPD activity 24-48 hours after 6422 administration to < 10% of 5-FU metabolized to FBAL compared to 80% reported for FDA approved capecitabine
- 24-48 hours after 6422 administration, 5-FU potency (systemic exposure per mg of capecitabine) was **approx. 50 x greater** than reported for FDA approved capecitabine
- The improved metabolism profile and increased **potency did not exist 7 days after a single dose of 6422**; the 6422 dosage regimen has been modified in amended Phase 1B protocol
- Need to identify a 6422 regimen that provides minimum exposure to 6422 while still inhibiting 5-FU metabolism such that < 10% of 5-FU is metabolized to FBAL
- The timeline of DPD inhibition and de novo formation needs to be evaluated in order to identify 6422 regimens that will inhibit DPD throughout capecitabine dosing

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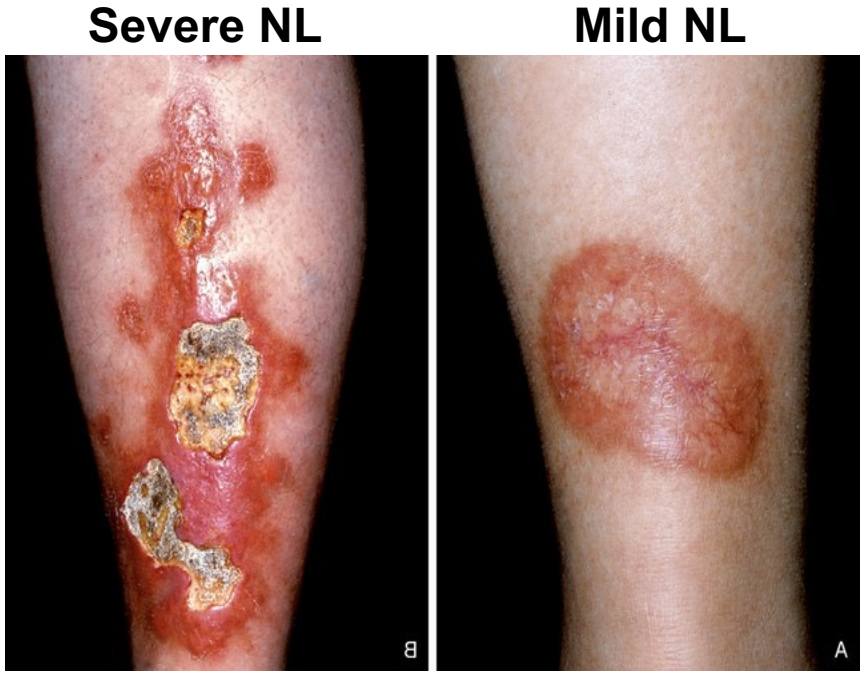
PCS499

Ulcerative Necrobiosis Lipoidica (uNL)

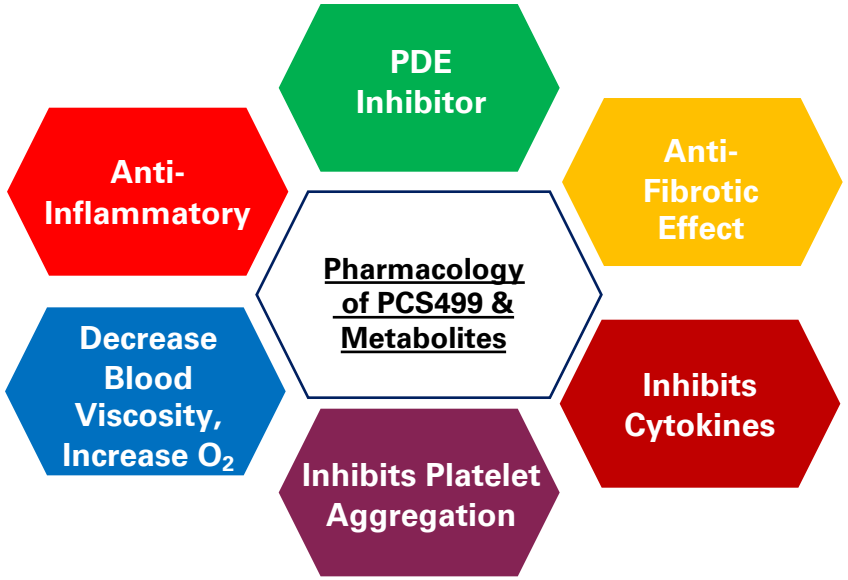
PCS499: Would be the First Drug Approved to Treat Ulcerative Necrobiosis Lipoidica (uNL) or Any Form of NL

- Skin and tissue below the skin become necrotic forming open ulcers; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports approximately 22,000 – 55,000 uNL patients in the U.S. will have painful ulcers occurring naturally or from contact trauma to the lesion
- Prevalence at any given time is probably significantly less
- Natural complete healing or wound closure of moderate to severe ulcers during the first 1-2 years after onset occurs in less than 5% of uNL patients
- No FDA approved treatment for uNL or NL, no standard of care, all treatments are inadequate
- Market potential of > $1B given the unmet medical need in this serious condition



Unmet Medical Need, Evidence of Clinical Efficacy

- No FDA approved treatment for uNL or NL, no standard of care, all treatments are inadequate
- Drugs have been used off-label with mixed success (e.g., pentoxifylline (PTX)); provide poor safety profile given their limited efficacy
- PCS499 is the deuterated analog of a major metabolite of PTX; has identical metabolites and pharmacological targets but PK of 499 and its metabolites is different than PTX and its metabolites, resulting in a better 499 safety profile and allowing for the administration of a higher, more efficacious dose of 499
- Pharmacological targets of 499 and its metabolites positively affect 6 of the 7 pathophysiological changes that can occur with NL

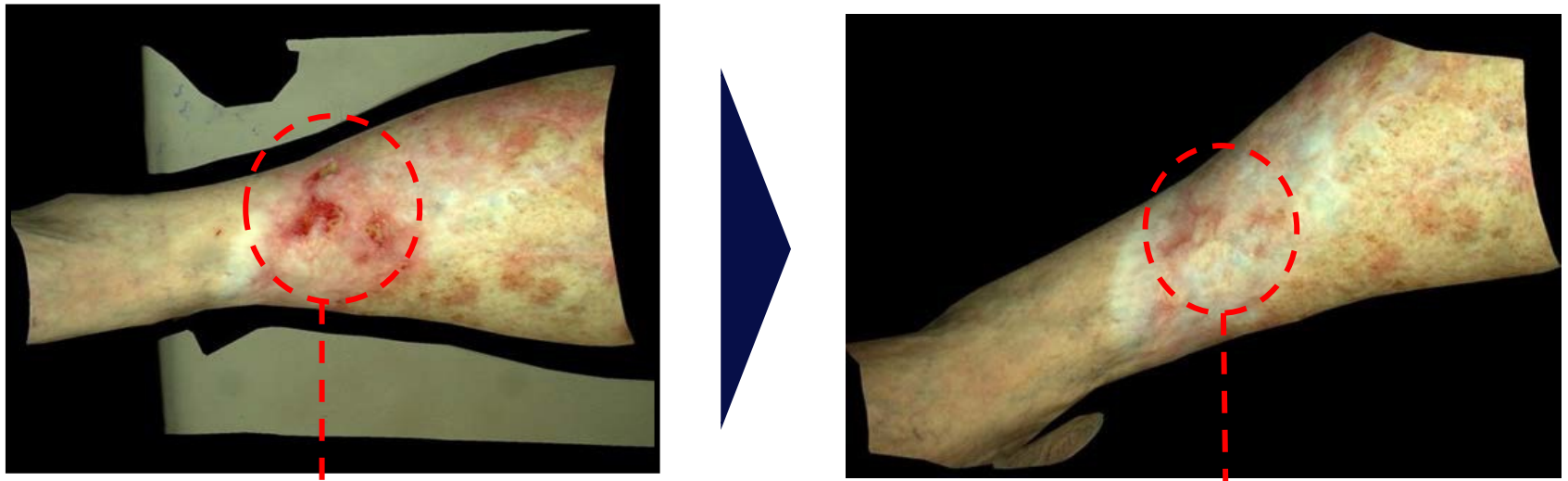


Pathophysiological Changes in NL

- **Decrease in blood flow & Oxygenation**
- **Decrease in platelet survival**
- **Increase inflammation**
- **Increase fibrosis**
- **Increase cytokines**
- **Degeneration collagen**
- Alters fat deposition

PCS499 in 2020 - 2021

- 1.8 gm/d of 499 has a better safety profile than 1.2 gm of PTX in animal tox studies and Phase 1 healthy human volunteer studies
- Determined 1.8 gm/d of 499 was safe in 12 NL patients and effective in closing the open ulcers of the 2 patients with uNL in an open-labeled Phase 2A trial



Baseline **Complete Closure**

- FDA has defined uNL as a serious condition based on communications with Processa
- Collaborated with FDA to define the information needed from a Phase 2B trial to guide us in the design of a single pivotal Phase 3 trial in 2023

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PCS12852

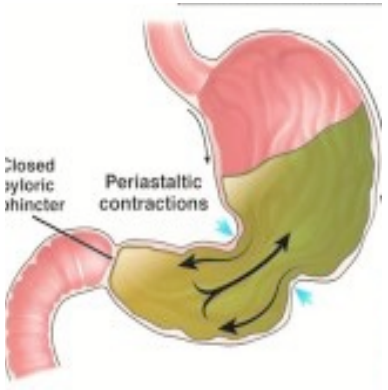
Gastroparesis

Gastroparesis

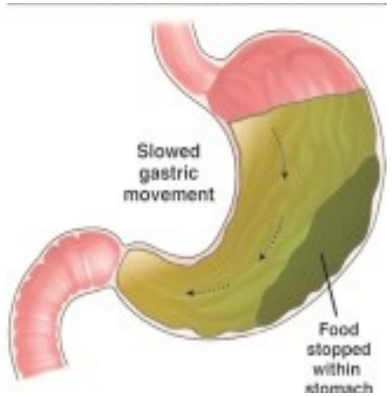
PCS12852 is a More Potent and More Selective 5HT4 Agonist than Previous 5HT4 Agonists

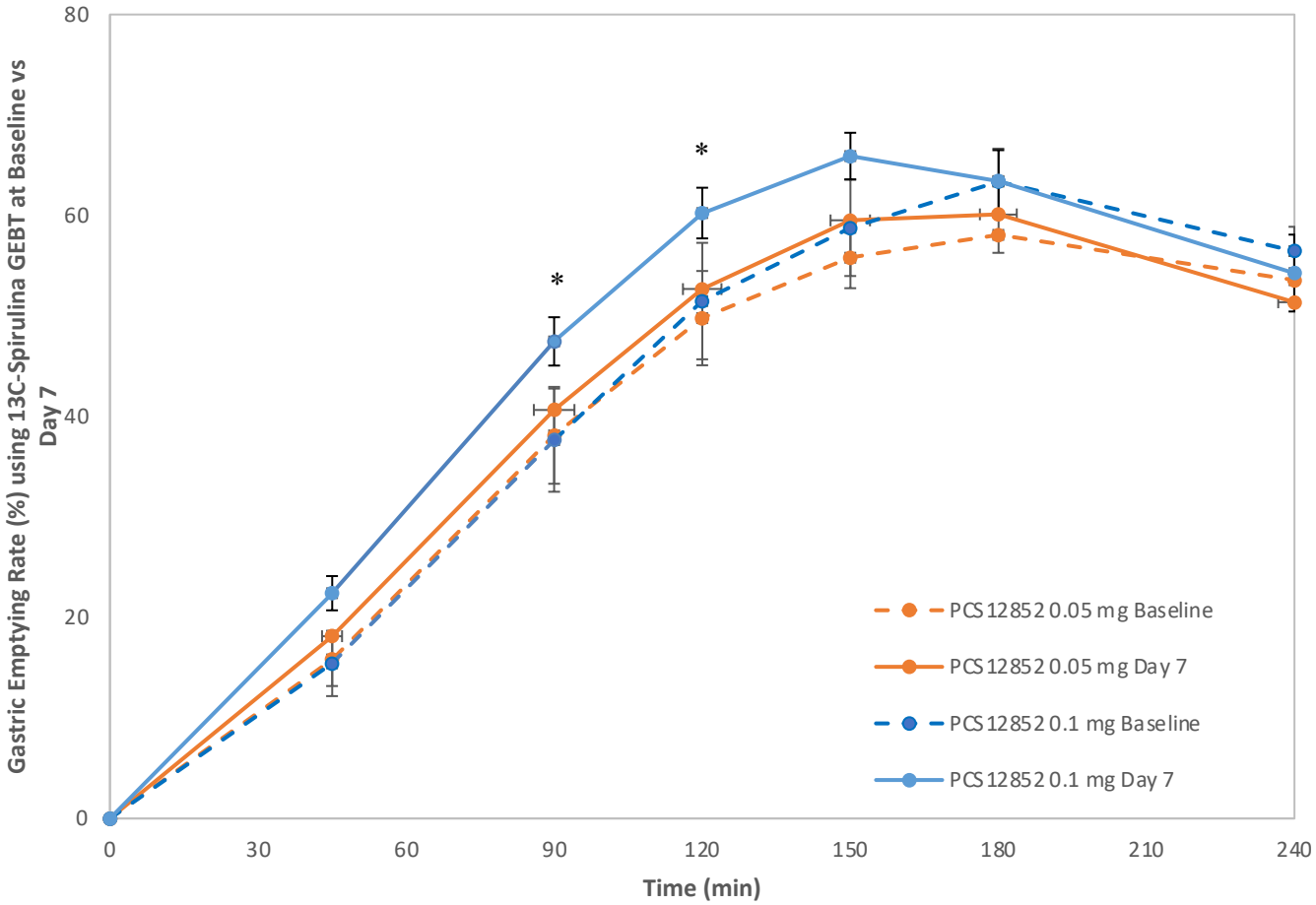
- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis (e.g., bloating, pain, nausea, vomiting)

Normal Gastric Emptying



Gastroparesis





Treatment of Gastroparesis (> $1.5B Market)

- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- All these drugs have a poor side effect profile limiting their use
- Present market size for gastroparesis is estimated to be over $1.5B

	PCS12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Target Population	• Potentially all gastroparesis patients (e.g., diabetic, idiopathic)	• Diabetic gastroparesis patients	• Diabetic gastroparesis patients
Binding	• Specific & potent 5HT4 receptor binding	• Less specific binding to 5HT4 than 12852 • Less potent than 12852	• Binds to Dopamine D2 receptors
Side Effects	• No serious side effects in clinical studies to date	• Serious cardiovascular side effects (e.g., cisapride removed from market) • Suicidal ideation (e.g., prucalopride)	• Black Box Warning serious neurological side effects, Side effects require limited use
Efficacy	• Increase gastric emptying rate in patients with constipation	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug FDA approved for treatment of gastroparesis

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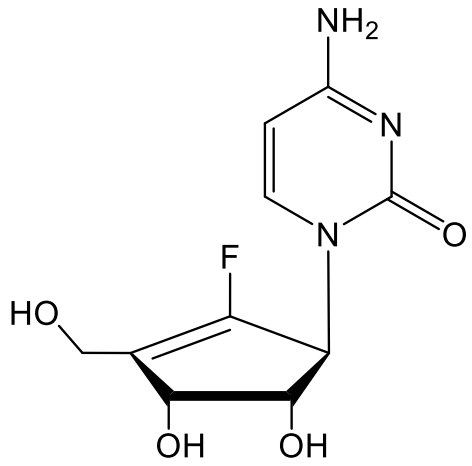
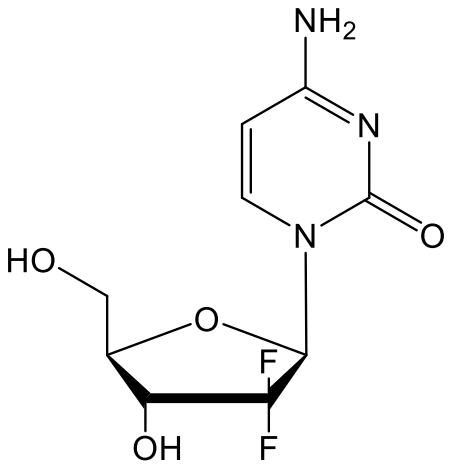
PCS3117
Metastatic Pancreatic Cancer, Biliary Cancer, Other Cancers

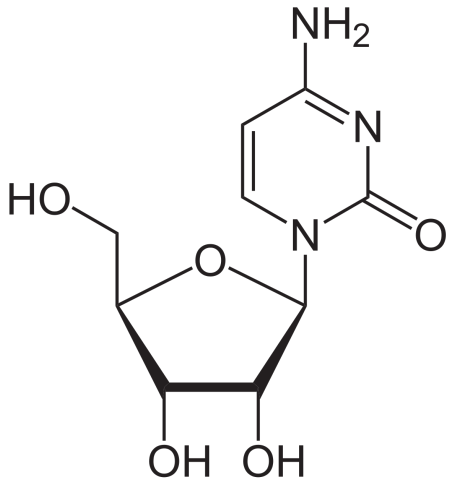
1H'22 - PCS3117 Biomarker Assay Development Completed



RX-3117
Oral Administration
(Cytosine + Ribose Analog)



Gemcitabine (dFdC)
IV Administration
(Cytosine + F,F-Deoxyribose)

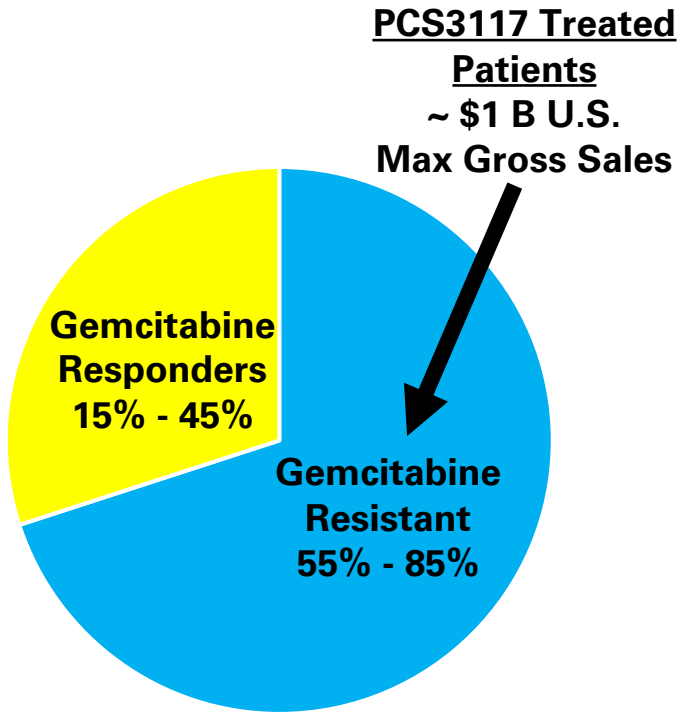


Cytidine
(Cytosine + Ribose Ring)

- Gemcitabine Market
  - First-line treatment for locally advanced or metastatic pancreatic cancer; inoperable, locally advanced or metastatic non-small cell lung
  - Second-line and third-line treatment for ovarian cancer and other types of cancer
  - Gross Sales: $815 M U.S., $1.7 B worldwide

PCS3117 for Cancer Patients Resistant to Gemcitabine

- PCS3117 has a similar structure to gemcitabine but is activated through a different pathway and causes cancer cell apoptosis in more ways than gemcitabine
- PCS3117 has been shown in gemcitabine resistant cancer patients and tumor animal models to alter cancer progression
- Gemcitabine is the most widely used chemotherapeutic agent used to treat pancreatic, non-small cell lung, and biliary cancer
- 55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance; inherent or acquired resistance is caused by
  - Increase in CDA enzyme activity breaking down gemcitabine but is less important for PCS3117
  - Deficiency in hENT1 decreases gemcitabine and PCS3117 transport through the cell membrane
  - Down-regulation of rate-limiting dCK enzyme decreases the formation of cancer-killing nucleotides but does not affect PCS3117 which is activated by UCK2 enzyme



PCS3117 Prior Evidence of Clinical Efficacy and Safety in Cancer Patients

- PCS3117 monotherapy Phase 2A trial as second or third-line therapy in patients with progressive metastatic pancreatic cancer after 1-5 previous therapies of chemotherapy (93% (40/43) refractory to gemcitabine)
  - 31 % (14 patients) had progression-free survival (PFS) for 2 months
  - 12% (5 patients) had stable disease for more than 4 months
  - One patient had a tumor reduction of 40% after 28 days of treatment
  - A previous report of gemcitabine as 2nd line therapy had only 17% disease-free progression
  - Mild to moderate adverse events reported with a better overall safety profile than gemcitabine
- PCS3117 + Abraxane Phase 2A trial as first-line therapy in chemotherapy naïve patients with metastatic pancreatic cancer
  - Overall response rate of 23% observed in patients (9/40)
  - Median progression-free survival of 5.4 months
  - Overall response rate was better than previous reports with only Abraxane
  - Overall response rate was no better than previous reports with gemcitabine + Abraxane

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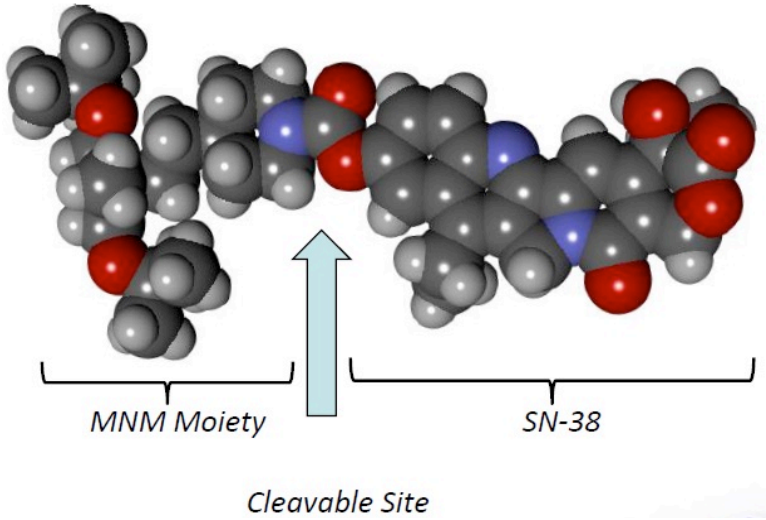
PCS11T

Small Cell Lung, Pancreatic, Colorectal, Other Cancers

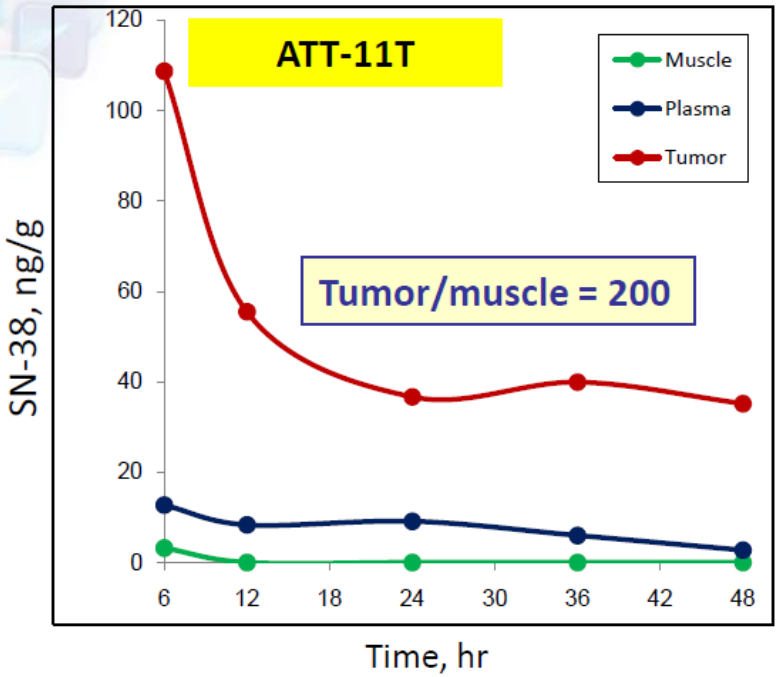
PCS11T: Lipophilic Prodrug of SN-38 (Irinotecan Active Metabolite)

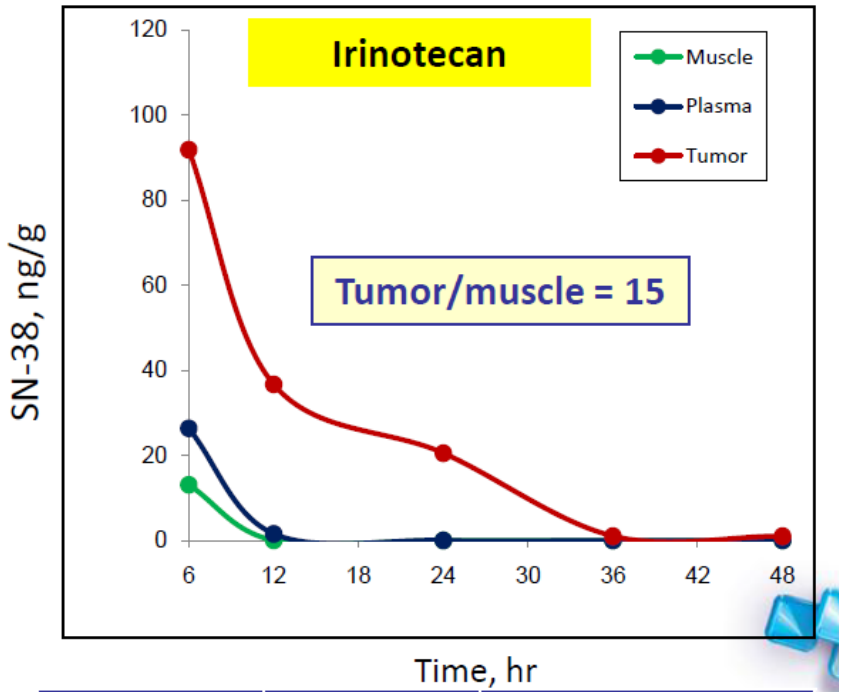
- Pro-drug of SN-38 linking SN-38 to a molecular nano-motor (MNM), a proprietary compound, which interacts with cell membranes preferentially accumulating in the membrane of tumor cells and the tumor core more than normal cells
- Creates an albumin/drug complex (similar conceptually to the albumin-paclitaxel complex in Abraxane) that extends the half-life of SN-38 by 5x compared to irinotecan in pre-clinical studies and likely decrease the side effects
- Given the MNM-SN38 specificity for cancer cells, upon approval it is unlikely that PCS11T will have the BlackBox diarrhea warning which irinotecan has
- Irinotecan sales prior to generics was > $1B



Higher and More Selective Tumor Exposure to SN38 with PCS11T (formerly ATT-11T) versus Irinotecan

Tumor-bearing mice had 200x higher drug in tumor vs muscle compared to 15x with Irinotecan

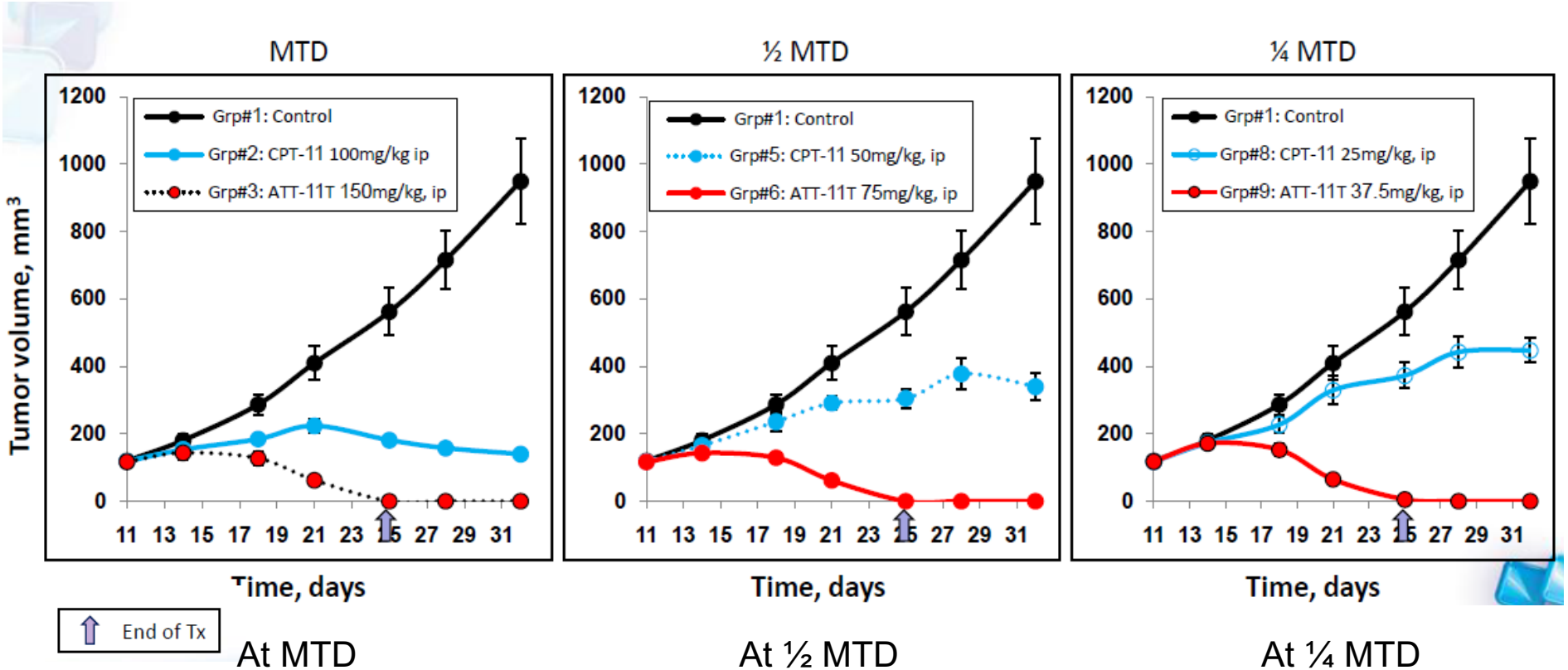




Tissue	AUC, ng/g*hr	Tumor/ organ ratio
Tumor	3,855	1
Plasma	403	9.57
Muscle	19.2	**200**

Tissue	AUC, ng/g*hr	Tumor/ Organ ratio
Tumor	1,153	1
Plasma	172	6.70
Muscle	78	**15**

Efficacy Maintained at Lower Doses of PCS11T When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model



At MTD
Tumor Growth Inhibition
100% ATT11-T
100% CPT-11

At ½ MTD
Tumor Growth Inhibition
100% ATT11-T
64% CPT-11

At ¼ MTD
Tumor Growth Inhibition
100% ATT11-T
53% CPT-11