Processa Pharmaceuticals

Clinical Pipeline Update
March 2022

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Processa Highlights

- **Development Company Focused on Improving the QOL or Survival of Patients with an Unmet Medical Need**
  - Present programs represent 5 different U.S. markets with potential sales of $500 M to $1.5 B for each drug
  - Each drug has the potential to expand into additional markets
- **Management & Development Team with Track Record of Success; Capital Efficient with SG&A ~ $4M/Year**
- **Regulatory Science Approach to Drug Development Initially Developed during FDA Collaborations 30 Years Ago and Refined over Time**
- **Continually Evaluating FDA Expedited Programs (e.g., Fast Track, Breakthrough, Accelerated Approval)**
- **Near Term Milestones (March-August)**
  - Next Generation Capecitabine: Re-start Phase 1B trial and determine the PCS6422 regimen to inhibit DPD activity for the 7 days of capecitabine dosing
  - PCS499: Complete enrollment of patients for interim analysis
  - PCS12852: Enroll the first patient in Phase 2A gastroparesis trial
  - PCS3117: Qualify biomarker assays
- **End of Year Milestones (September–December)**
  - Next Generation Capecitabine: Complete enrollment of Phase 1B trial and preliminarily determine Maximum Tolerated Dose (MTD) for capecitabine
  - PCS499: Complete enrollment of patients for trial and obtain top-line results on interim analysis
  - PCS12852: Complete enrollment of patients in Phase 2A trial
  - PCS3117: Define potential development programs for approval in multiple cancers
- **2023 Milestones U.S.**
  - With final results from 3 clinical trials in 3 different indications, initiate at least one pivotal registration trial and one Phase 2 trial

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**

Processa Pipeline – Five Drugs Each with $1B Market Opportunity

Multiple High Value Milestones in 2022

Drug	Disease Target	Nonclin	Phase 1	Phase 2	Phase 3	Status	2022 Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica					3 Patients Dosed; 3 Patient in Pre-Screening; Adding Sites	1H'22 – Complete Interim Group Enrollment 2H'22 - Interim Analysis, Complete Enrollment
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders					Initiating Trial Sites; Screening Patients	1H'22 - FPI Phase 2A; 2H'22 - Complete Enrollment
PCS3117 Phase 2B	Pancreatic, Other Cancers					Biomarker Assay Started; Development Programs Being Evaluated	1H'22 - Qualify Biomarker Assays, 2H'22 - Define Development Program and Design Clinical Trials
Next Generation Capecitabine Phase 1B (PCS6422)	Metastatic Colorectal, Breast, Other Cancers					Cohort 1&2 no DLTs; 6422 Regimen Alters 5-FU Metabolism for 1-2, not 7 Days; Modified Protocol Submitted to FDA	1H'22 - Restart Phase 1B, Identify 6422 Regimen; 2H'22 - Complete Enrollment
PCS11T Pre-IND	SC Lung, Other Cancers					Development on Hold Given Lack of Funds	

Blue - Use of Existing Cash

FPI – First Patient In (i.e., randomized)
MTD – Maximum Tolerated Dose

Next Generation Capecitabine - Capecitabine Combined with PCS6422

- Modified Phase 1B protocol to evaluate timeline of DPD enzyme inhibition - de novo formation
  - 75 mg b.i.d. of capecitabine after a single dose of 6422 in Cohort 2 was safe but did not alter the effect of DPD throughout the 7 days of capecitabine dosing
  - Modified protocol to evaluate 2-3 PCS6422 dosage regimens with the 75 mg b.i.d. capecitabine; submitted to FDA in February 2022
  - Added to the protocol: 1) evaluate DPD inhibition/de novo formation timeline, 2) determine regimen of 6422 to inhibit DPD to < 10% of normal over 7 days of capecitabine dosing, 3) determine the potential for Next Generation Capecitabine to be dosed using an Individualized or Personalized Cancer Therapy approach
- No requirement for FDA to approve or communicate with us regarding modified protocol and we can move forward prior to their review; we are modifying the database/informed consent and submitting documents for IRB approvals
- Re-initiating sites now; investigators excited about restarting the program; also adding 1-3 sites
- Expect to restart dosing in 1H'22; initial evaluation of DPD timeline should occur June/July; determine MTD of Next Generation Cap/6422 regimen in 4Q'22 since the study is open labeled
- Expect Phase 2B or adaptive designed Phase 3 to begin 2H'23

PCS499 – Ulcerative Necrobiosis Lipoidica (uNL)

- 3 patients enrolled; preliminary results show ulcers may have closed in some patients
- 3 patients in pre-screen (identified through pictures to have an ulcer(s), expressed interest in being screened)
- COVID-19 has affected enrollment (patients in pre-screen died from COVID, patients identified but not willing to travel)
- Prevalence of ulcerated NL likely much less than 22,000 – 50,000 (literature estimation)
- In 4Q'21 began putting in place remedial efforts to improve patient enrollment; efforts still ongoing
- Closed ex-US sites not successful in enrolling patients; replacing ex-US sites with 2-5 US and/or new ex-US sites
- Enrollment of 6 -10 patients for interim analysis should be completed by 7/1/22; interim results expected December 2022
- Evaluating other pathways to approval given the difficulty in enrolling patients

PCS12852 and PCS3117

- PCS12852 (Gastroparesis)
  - Sites being initiated; the 1st two patients are in screening; expected FPI 1H'22
  - Complete enrollment in 4Q'22 with preliminary topline efficacy results in Dec 2022 – Jan 2023

- PCS3117 (Metastatic Pancreatic and Other Cancers)
  - Developing biomarkers to determine if high probability responders to 3117 can be defined prior to treatment so that 3117 can be used following a Precision Medicine approach to therapy
  - Developing drug development plans for
    - 1st line therapy for recurrent pancreatic cancer after surgery with Adjuvant Chemotherapy (FOLFIRINOX - folinic acid, fluorouracil, irinotecan, and oxaliplatin),
    - 2nd or 3rd line therapy in metastatic pancreatic cancer, and
    - 1st or 2nd line therapy in the treatment of biliary tract cancer

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Our People Lead to Success

Management Team

David Young, PharmD. PhD
Chief Executive Officer, Chairman of the Board

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

David Young, PharmD. PhD
Chairman of the Board, CEO

Justin Yorke
Independent Director
Manager of the San Gabriel Fund, JMW Fund and the Richland Fund

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

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

Khalid Islam, PhD
Director
Former CEO of Gentium
Chairman of the Board of Fennec Pharm.

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Pipeline Backup Slides

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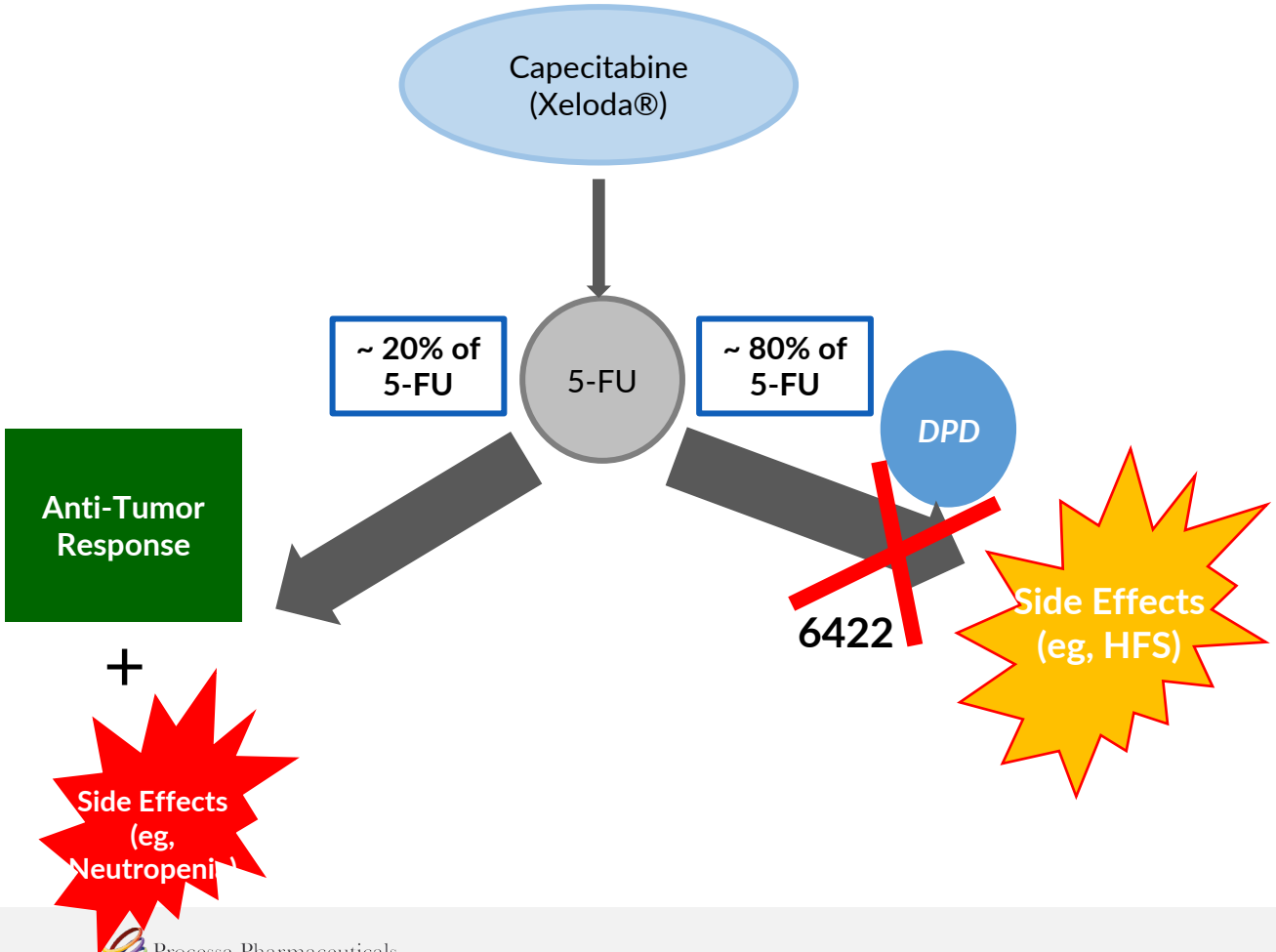
Next Generation Capecitabine (Combination of Capecitabine with PCS6422)

Metastatic Colorectal Cancer

Next Generation Capecitabine (Combination of PCS6422 and Capecitabine): Interim Results in GI Cancer (> $1B Market)

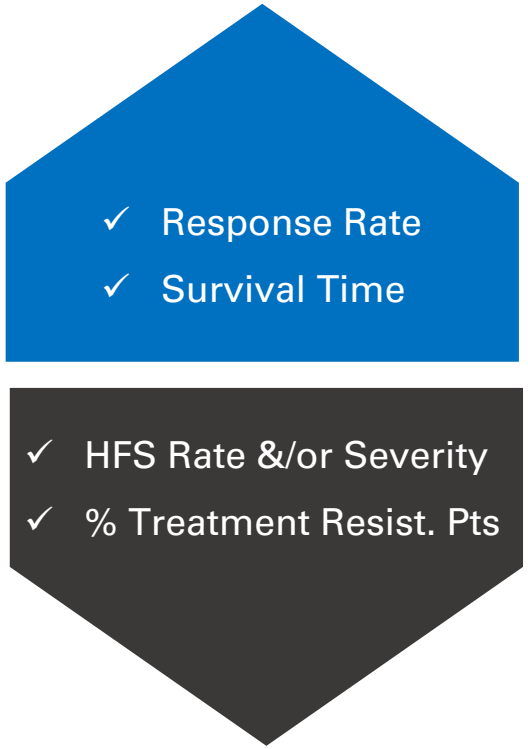
When PCS6422 Irreversibly Inhibits DPD, Next Generation Capecitabine Should be More Potent Than FDA Approved Capecitabine



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 PCS6422 inhibited DPD activity 24-48 hours after PCS6422 administration with < 10% of 5-FU metabolized to FBAL compared to 80% reported for FDA approved capecitabine
- 24-48 hours after PCS6422 administration, 5-FU potency, based on systemic exposure per mg of capecitabine, was at least 50 x greater than reported for FDA approved capecitabine
- The improved metabolism profile and increased potency did not exist 7 days after PCS6422 administration; the Phase 1B protocol and PCS6422 dosage regimen has been modified

Next Generation Capecitabine: Next Steps and "Audible" Call by Processa



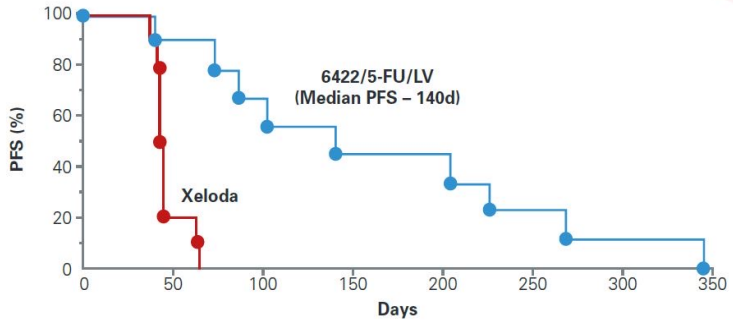
- Since 6422 irreversibly inhibits DPD, metabolism to FBAL after 6422 administration occurs from some DPD not being inhibited and/or the formation of new DPD molecules
- The timeline of DPD inhibition and de novo formation will be further evaluated in order to identify 6422 regimens that will inhibit DPD throughout capecitabine dosing
- The modified Phase 1B protocol has been submitted to FDA
- Processa expects to restart enrollment of patients in 1H'22 and define the Next Generation Capecitabine regimens for both 6422 and capecitabine by end of 2022
- The overall timeline for initiation of Phase 2B/3 trial (2023-2024) and NDA submission (2027-2028) is not expected to change; additional DPD information may offer a personalized therapeutic drug monitoring approach to treating each cancer patient

Unmet Medical Need, Evidence of Clinical Benefit, Regulatory Science Platform

- 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
- Regulatory Science
  - Measuring biomarker(s) may help to increase the probability of successful treatment and provide a personalized/individualized approach to treating patients with Next Generation Capecitabine
  - 6422+capecitabine combination provides patients with a better benefit-risk profile (less adverse events and/or better efficacy) than just capecitabine

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

Adherex files & Rivera E et al, 2014. Clin. Breast Cancer

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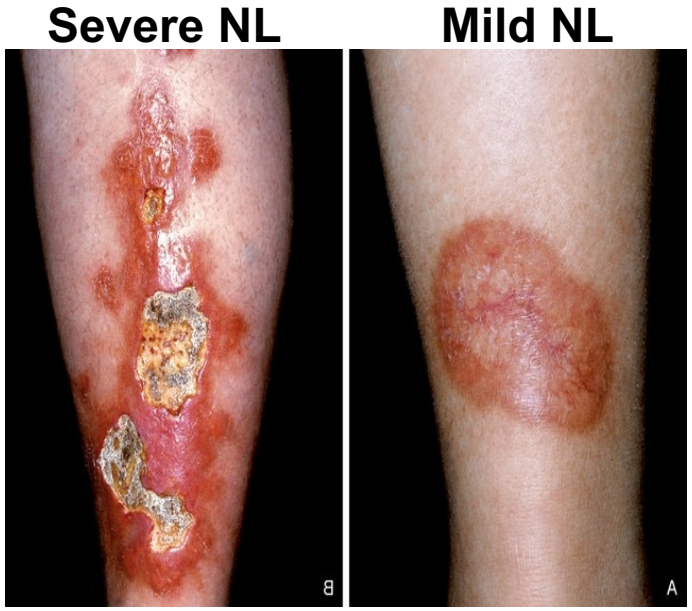
PCS499

Ulcerative Necrobiosis Lipoidica

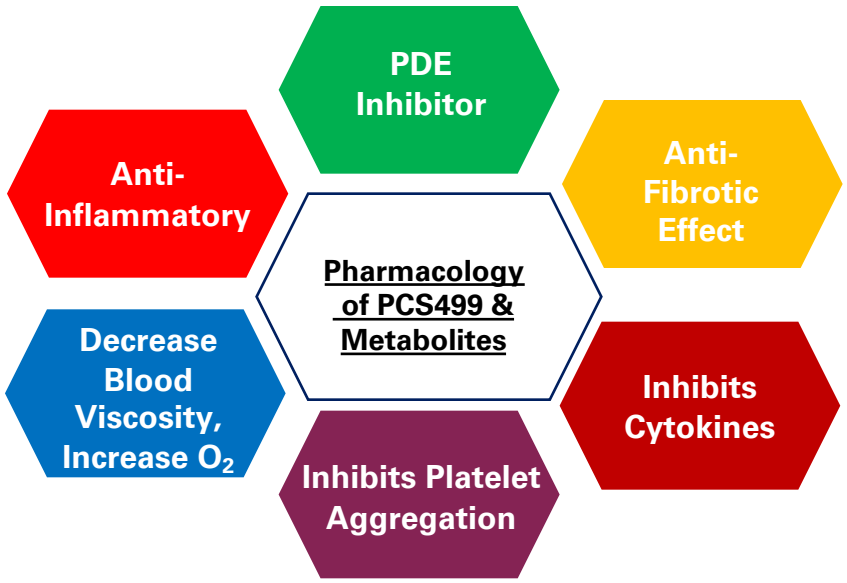
PCS499: First Drug to Treat Ulcerative Necrobiosis Lipoidica (uNL)

- Skin and tissue below the skin becomes necrotic; can last from months to years with complications such as infections, amputation, and cancer
- Literature reports approximately 22,000 – 55,000 uNL patients in U.S. with painful ulcers occurring naturally or from contact trauma to the lesion (numbers may actually be 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 these patients
- Market potential of > $1B even if the prevalence of uNL is significantly less



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 + metabolites is different than PTX + metabolites resulting in a better 499 safety profile and allowing the administration of a higher, more efficacious dose of 499

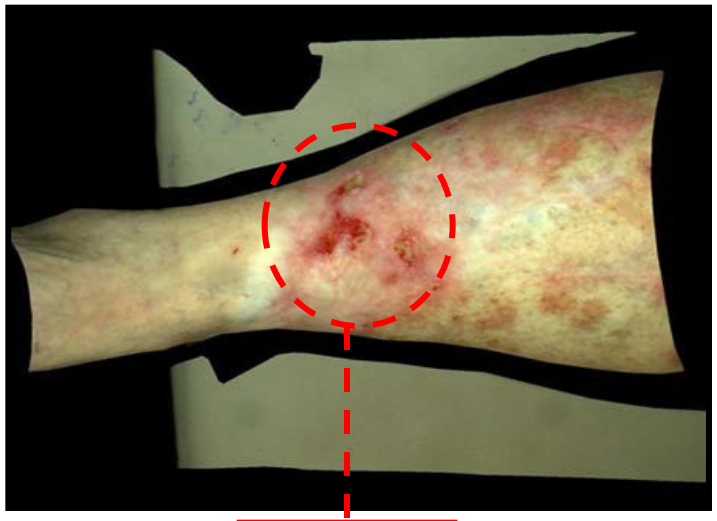


Pathophysiological Changes in NL

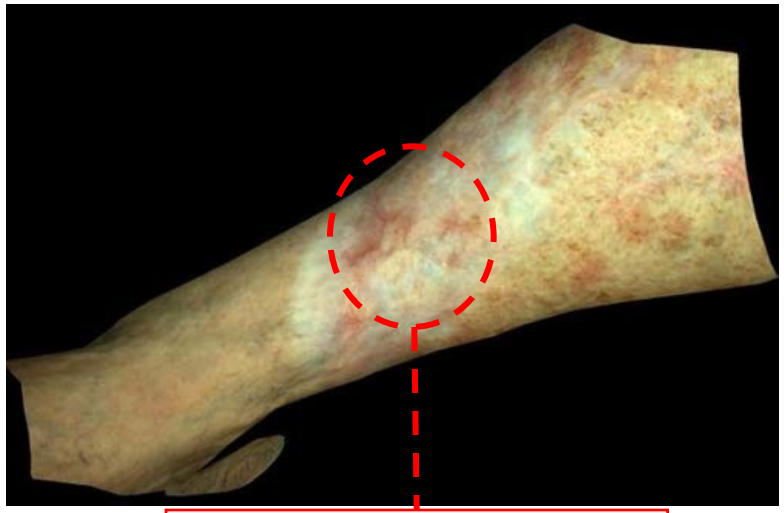
- **Decrease in blood flow & Oxygenation**
- **Decrease in platelet survival**
- **Increase inflammation**
- **Increase fibrosis**
- **Increase cytokines**
- **Degeneration collagen**
- Alters fat deposition

Phase 2A PCS499 Improves Benefit-Risk Profile

- 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
- In the Phase 2A study of 10 NL and 2 ulcerative NL patients, all ulcers closed in the 2 ulcerative NL patients, including new contact trauma ulcers and 1.8 gm/d was well tolerated in all patients
- Non-ulcerated patients reported improvement in NL but clinical significance could not be determined



Baseline



Complete Closure

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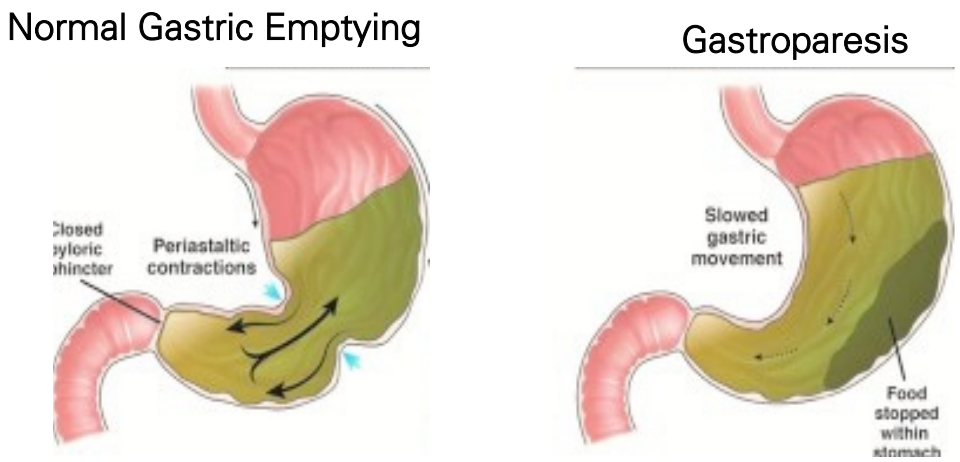
PCS12852

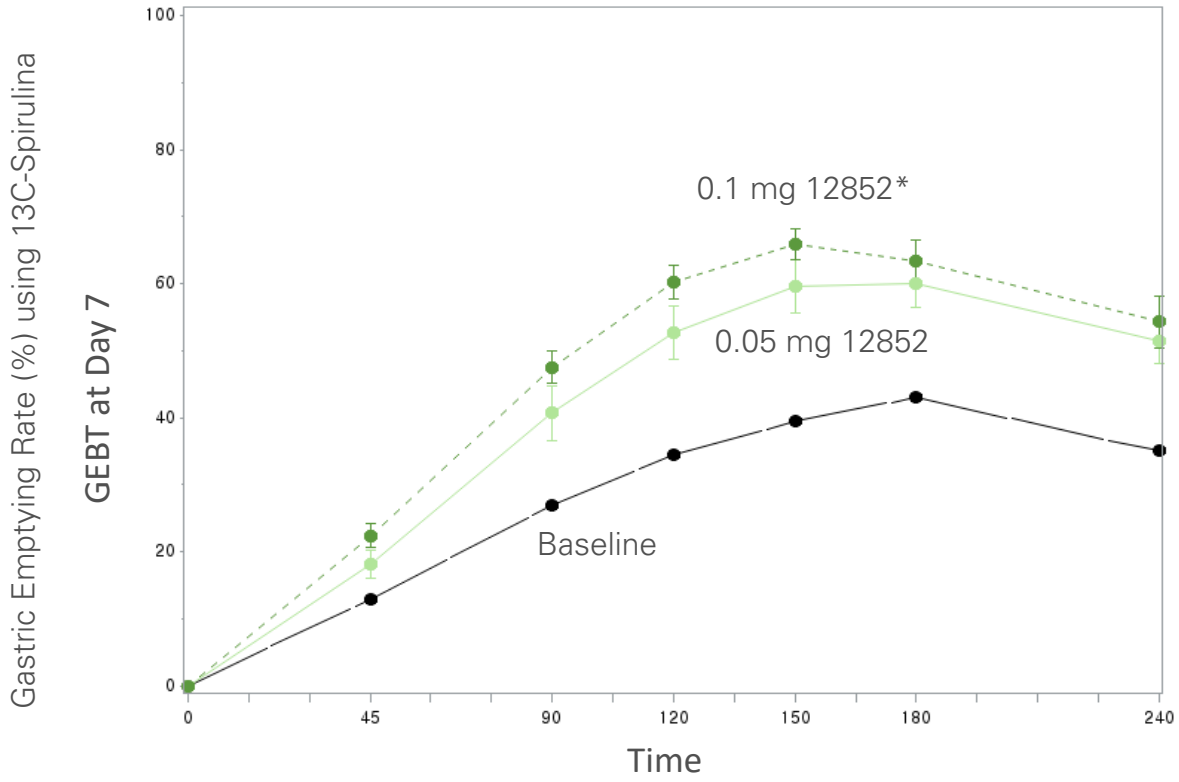
Gastroparesis

2H'22 - PCS12852 Trial Conduct Completed

PCS12852 Potent and Selective 5HT4 Agonist for Treatment of Gastroparesis

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





PCS12852: Potent & Selective 5HT4 Agonist for Treatment of Gastroparesis ($1B Market)

	PCS12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
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

- Existing FDA approved drugs and off-labeled used drugs have poor side effect profiles limiting their use in chronic gastroparesis
- Phase 2A is a placebo-controlled, randomized, dose-response trial evaluating the gastric emptying rate in gastroparesis patients as well as gastroparesis symptoms
- Site activation and patient screening has started
- FPI for Phase 2A expected 1H'22 with completion of study conduct 4Q'22
- Final analysis of Phase 2A expected Dec 2022-Jan 2023
- Primary endpoints in Phase 2B and Phase 3 trials will be based on symptoms

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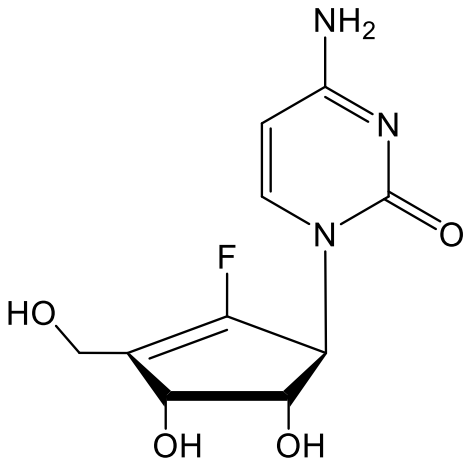
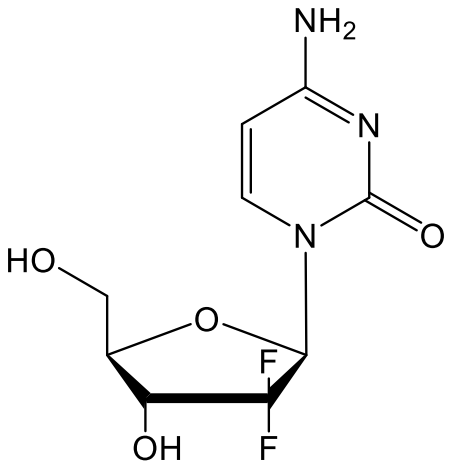
PCS3117

Metastatic Pancreatic Cancer

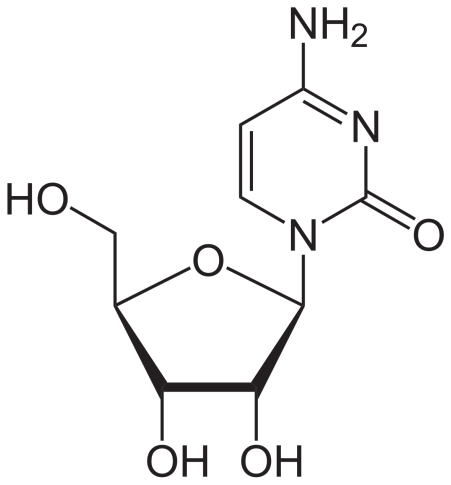
1H'22 - PCS3117 Biomarker Assay Development Completed



RX-3117
Oral Administration
(Cytosine + Ribose Analog)



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



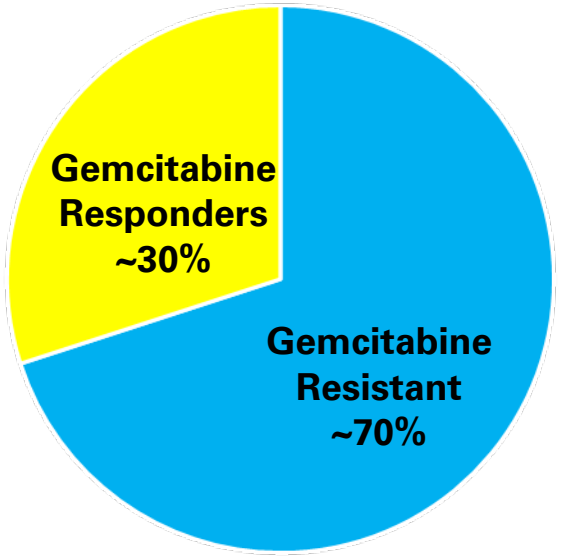
Cytidine
(Cytosine + Ribose Ring)

- 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

Gemcitabine Resistant Patients

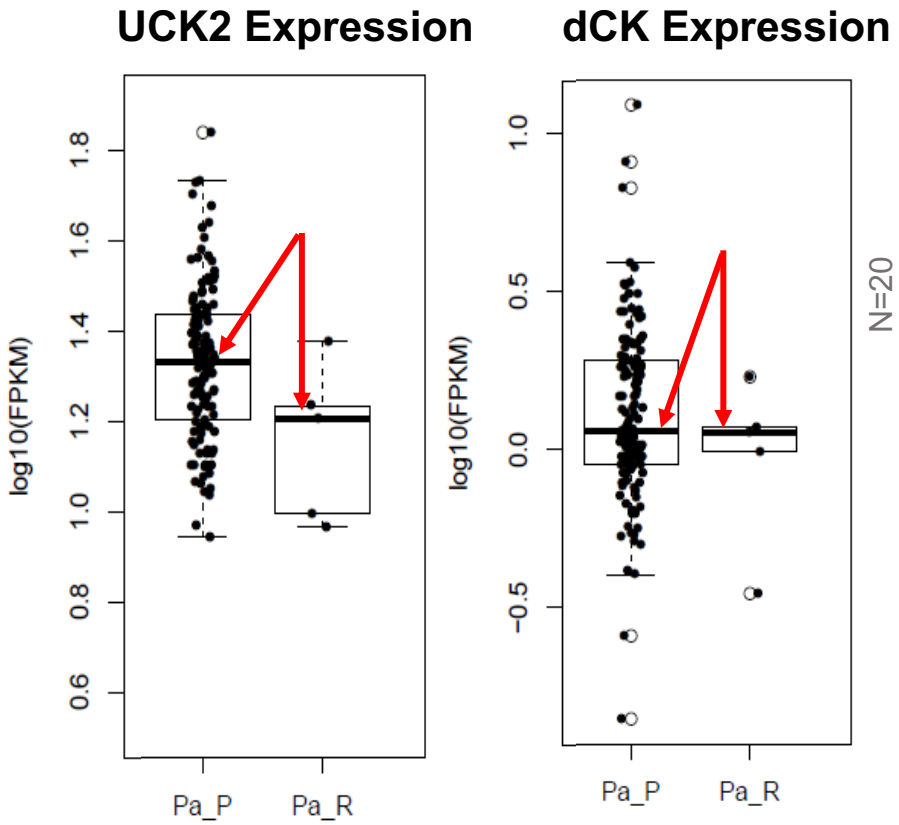
- 55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance
  - Gemcitabine's overall response or disease control rate is 15% to 45% depending on the type of cancer and trial
  - Inherent or acquired resistance caused by
    - ✓ Increase in CDA activity
    - ✓ Deficiency in hENT1 - decreases gemcitabine transport through the cell membrane
    - ✓ Down-regulation of rate-limiting dCK enzyme – decreases the formation of cancer-killing nucleotides
    - ✓ Up-regulation of RRM1/RRM2 - increases the formation of endogenous cytidine nucleotide
    - ✓ Nongenetic influences on gene expression - genetic and epigenetic abnormalities

Gemcitabine Treated Patients
$815 M U.S. - $1.7 B Worldwide Max Gross Sales



Target Population: More Likely to Respond to or Activate PCS3117 than Gemcitabine

- 3117 is metabolized to its active metabolite through a different route than gemcitabine; has a different MOA than gemcitabine
- Treat patients more likely to respond to 3117 than gemcitabine
- Biomarker assays are being developed to potentially define a targeted, personalized medicine approach to identifying patients who will respond to 3117 better than gemcitabine
- Patients more likely to respond to or activate 3117 than gemcitabine
  - Patients with high UCK2 enzyme levels
  - Patients who catabolize (breakdown) 3117 less than gemcitabine
  - Patients who have inherent or acquired resistance to gemcitabine but not 3117
- 3117 has FDA Orphan Designation for pancreatic cancer and patents to 2036



Pa_P : Pancreatic Tumor, N=134
Pa_R : Normal pancreas, N=5
(Data from Univ. of Toronto)

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