Processa Pharmaceuticals

2Q 2021 Earnings Call | August 12, 2021

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Processa's Differentiated Approach

Repeatable, Capital-efficient Blueprint Platform with Potential to Generate Significant ROI

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**

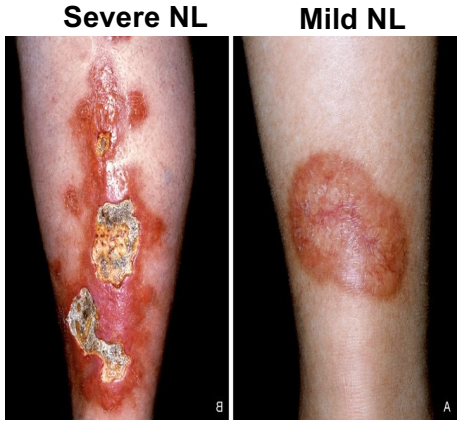
Processa Pipeline – Multiple Opportunities For Success

Drug	Disease Target	Preclin	Phase 1	Phase 2	Phase 3	Status	Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			→ *		2 Patients Enrolled; 1 Patient in Screening; 10 Patients Pre-Screen Failures; 3/9 Sites Active	Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders			→		IND Being Reviewed and Finalized	Phase 2A IND Submission 3Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			→ *		Biomarker Assay Lab Being Selected and Protocols Being Prepared	Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22; FPI Phase 3 SPA 2023 – 2024
PCS6422 Phase 1B	Metastatic Colorectal, Breast Cancer		→ *			1 Patient Enrolled; 1 Patient Pre-Screen Failure; 2 Patients in Screening Waiting Room; 4/5 Sites Active	Interim Cohort Analysis 4Q'21; MTD Determined 2H'22; FPI Phase 2B/3 2023 – 2024
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer	→				CMOs Being Evaluated	Complete IND Enabling Studies; Phase 1B IND Submission 1H'23

* Cleared by FDA for Clinical Trial

FPI – First Patient In (i.e., randomized)
SPA – FDA Special Protocol Assessment
MTD – Maximum Tolerated Dose

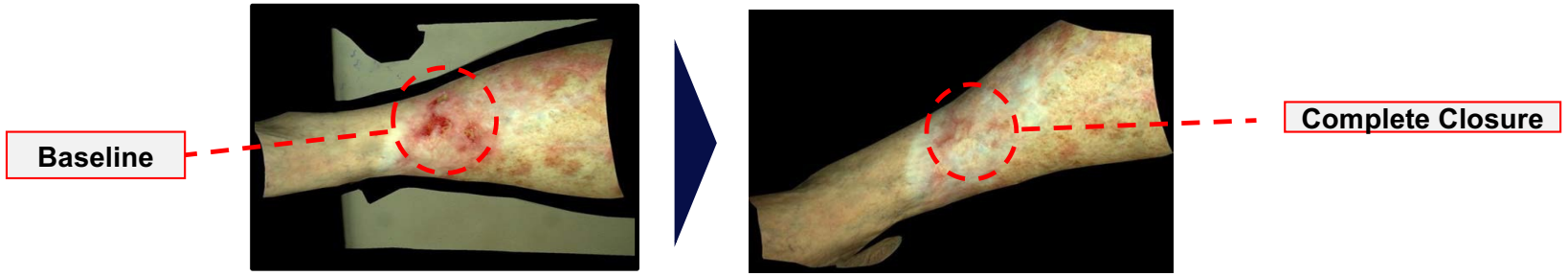
PCS499 to Be First to Market for the Treatment of Ulcerative Necrobiosis Lipoidica (uNL)



- Skin, tissue below the skin becomes necrotic, last from months to years with complications such as infections, amputation; Histopathology ≠ diabetic ulcers
- 30% of NL patients have painful ulcers occurring naturally or from contact trauma;
- Natural complete healing of moderate to severe ulcers in less than 5% of these patients during the first 1-2 years after onset
- **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)) - side effect profile, limited efficacy
- Economic Value: Initial Market
  - 75,000 – 185,000 NL patients in U.S.
  - 22,000 – 55,000 uNL patients in U.S.
  - 499 has orphan designation for NL (7-year market exclusivity) and patent exclusivity until 2030
  - **U.S. market potential in uNL is ~ $1 B annual gross sales**

Unmet Medical Need, Evidence of Clinical Efficacy, PCS499 Improves Benefit-Risk

- **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**
- **499 + metabolites target pharmacology that directly affect 6 of the 7 NL pathophysiological changes**
- **1.8 gm/d of 499 has 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, a**ll ulcers closed** in the 2 ulcerative NL patients, **including new contact trauma ulcers, and 1.8 gm/d was well tolerated**

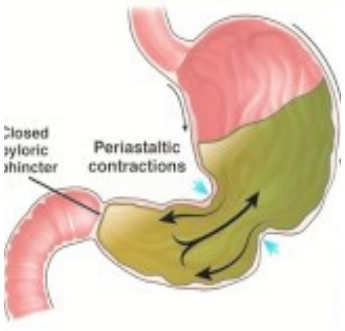


Status	Milestones
2 Patients Enrolled; 1 Patient in Screening; 10 Patients Pre-Screen Failures; 3/9 Sites Active	Interim Analysis 1H'22; Final Analysis 2H'22; FPI Phase 3 SPA 2023

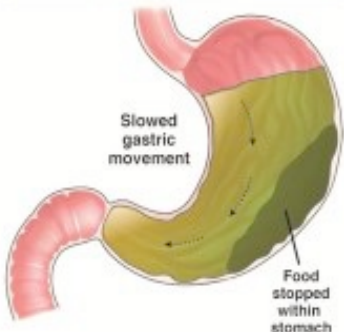
PCS12852 Potent-Selective 5HT4 Agonist: Gastroparesis ($1 B Market)

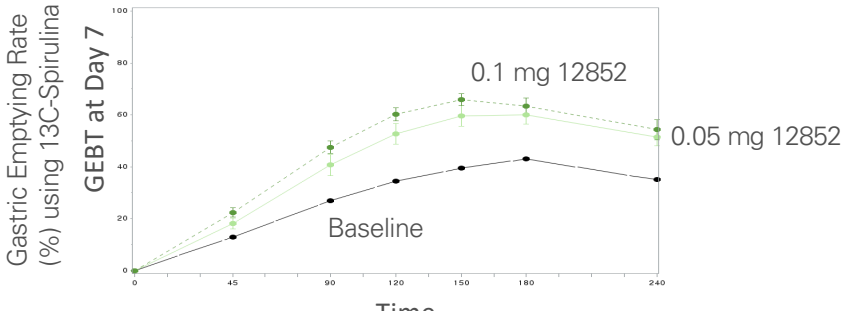
Submit IND for Phase 2A Trial in 3Q'21, FPI in 1Q'22

Normal Gastric Emptying



Gastroparesis





	12852	Other 5HT4 Drug (e.g., Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (.e.g,, Metoclopramide)
Binding	• Very specific 5HT4 Agonist • Very potent to 5HT4	• 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 CV side effects** (e.g., cisapride removed from market) • Suicidal ideation	• Black Box Warning **serious neurological side effects**
Efficacy	• Increase gastric emptying rate • **Gastroparesis patient study required**	• Increase gastric emptying rate • Successful treatment demonstrated	• Only drug approved for treatment of gastroparesis

PCS12852 Potent-Selective 5HT4 Agonist for Treatment of Gastroparesis

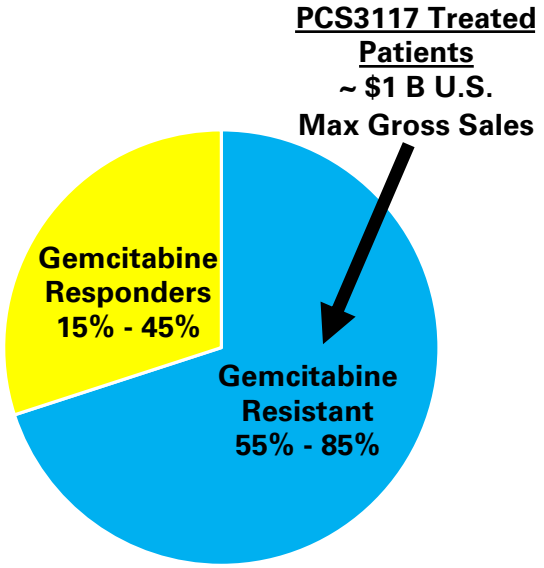
➢ Economic Value: Initial Markets

- Prevalence of moderate to severe gastroparesis in U.S. reported to be over 200,000 to > 1,500,000 patients depending on formal diagnosis vs symptom presentation
- Present use of approved drugs and off-labelled drugs in gastroparesis is limited by side effects
- U.S. market potential is $500 M to > $1.5 B

Status	Milestones
IND Being Reviewed and Finalized	**Phase 2A IND Submission 3Q'21; FPI Phase 2A 1H'22; Final Analysis 2H'22 - 1H'23**

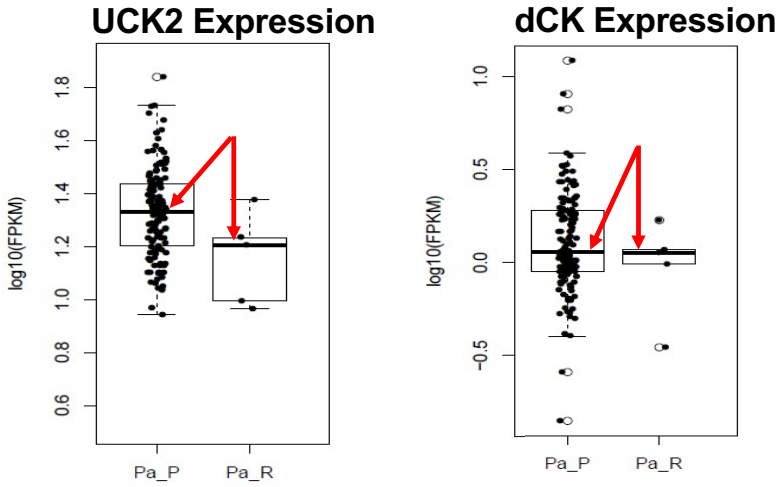
In Licensed PCS3117 for Gemcitabine Resistant Pancreatic and Lung Cancer Patients

- PCS3117 has 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 and non-small cell lung cancer
- **55% - 85% of patients are inherently resistant to gemcitabine or acquire resistance**; inherent or acquired resistance 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 formation of cancer killing nucleotides but does not affect PCS3117 which is activated by UCK2 enzyme
  - Up-regulation of RRM1/RRM2 increases formation of endogenous cytidine nucleotide while increases production of cancer killing PCS3117 nucleotides



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

- **Biomarker assays are being developed and evaluated** 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 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**

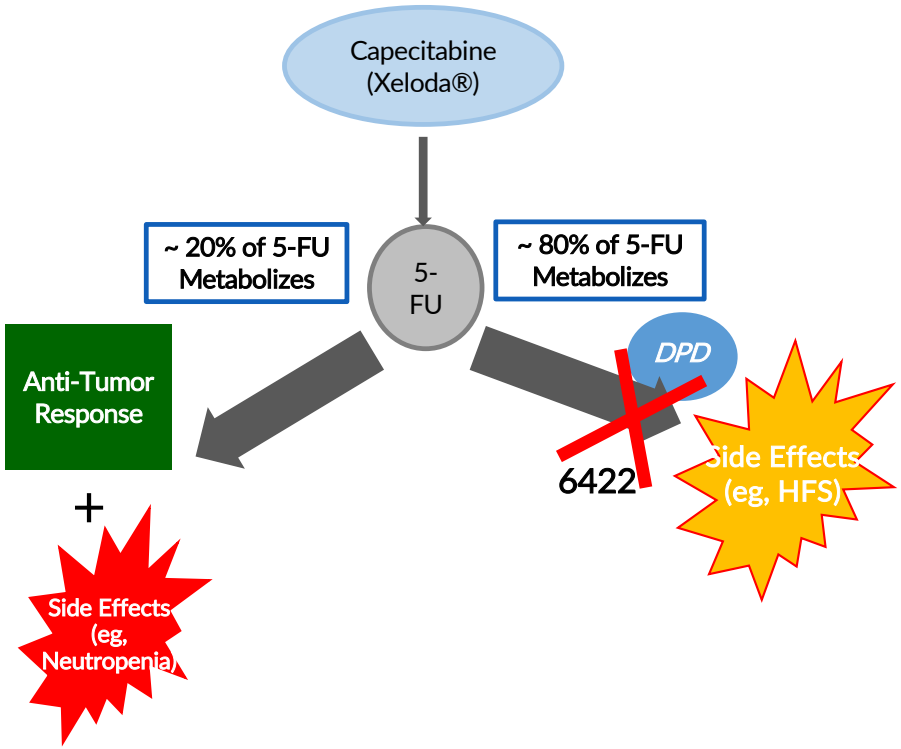


Pa_P : Pancreatic Tumor, N=134
Pa_R : Normal pancreas, N=5
(Data from Univ. of Toronto)

Status	Milestones
Biomarker Assay Lab Being Selected and Protocols Being Prepared	**Complete Biomarker Assays 1H'22;** **FPI Phase 2B 2H'22;** **FPI Phase 3 SPA 2023 – 2024**

PCS6422 Combined with Capecitabine To Provide Better Safety/Efficacy Profile

PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



<u>6422 Inhibits DPD Allowing Two Ways to Win</u>

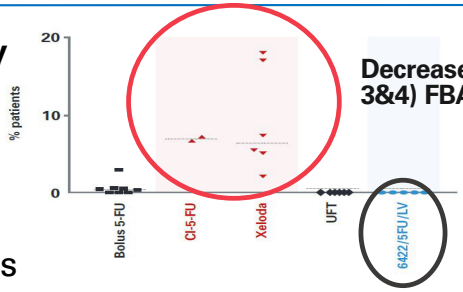
- **<u>Lower Side Effects</u>** by Lowering 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations
- **<u>Improve Capecitabine Efficacy</u>** – Potentially Increase Response Rate by Increasing Tumor Exposure to Cancer Killing 5-FU Metabolites

<u>Economic Value: Initial Markets</u>

- 6422 + Capecitabine combination potentially 1st line therapy for a number of cancers (e.g., metastatic colorectal and breast cancer)
- 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>U.S. market potential in colorectal cancer is ~ $1.0 B</u>**

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
- **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

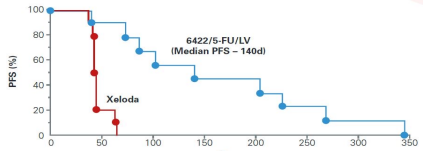


Decrease Incidence of HFS (Grade 3&4) FBAL Side Effects

Revollo et al. 2008 Clin Cancer Res; Masuda et al. 2019. NEJM

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

Status	Milestones
1 Patient Enrolled; 1 Patient Pre-Screen Failure; 2 Patients in Screening Waiting Room; 4/5 Sites Active	**Interim Cohort Analysis 4Q'21; MTD Determined 2H'22; FPI Phase 2B/3 2023 – 2024**

Summary Timeline of Pipeline and Key Clinical Milestones

	1H 2021	2H 2021	1H 2022	2H 2022	2023-2025
PCS499 Phase 2B	• Initiate Sites • FPI		• **Interim Analysis**	• **Final Analysis**	• **Phase 3 Trial** • NDA Submission
PCS12852 Phase 2A	• Pre-IND Meeting • Prepare IND	• **IND Submission (3Q'21)** • Select CRO; Initiate Sites	• **FPI**	• **Final Analysis**	• **Final Analysis** • **Phase 2B Trial** • **Phase 3 Trial**
PCS3117 Phase 2B	• Licensed	• Initiate Biomarker Assay Development	• **Complete Biomarker Assay Development**	• **Initiate Sites** • **FPI**	• **Phase 3**
PCS6422 Phase 1B	• Initiate Sites • FPI	• **Interim Analysis 4Q'21**		• **Determine MTD** • **Initiate Dose Confirmation Stage 2**	• **Final Analysis Stage 2** • **Phase 2B/3 Trial**
PCS11T IND	• Evaluate CMOs	• Evaluate CMOs	• Initiate Tox		• Complete Tox • Complete IND • **IND Submission**

FPI – First Patient In
CMO – Contract Manufacturing Organization
CMC – Chemistry, Manufacturing, Control

What's Expected Over the Next 6 Months?

- Complete enrollment of patients for the interim analysis of PCS499
- IND Clearance for PCS12852 in Gastroparesis
- Analysis of Cohort 1 & 2 in the 6422 Phase 1B Dose Escalation Study
- Development of PCS3117 Biomarker Assays and Initiation of Assay Validation
- Invited Presentation: World Orphan Drug Congress USA 2021, Aug 25 - 27, 2021
- Invited Presentation: Oppenheimer Fall Healthcare Life Sciences & MedTech Summit, Sept 20-23, 2021
- Research Analyst Reports:

  Robin Garner – Craig Hallum

  Aydin Huseynov - Benchmark

  Hogan Mullaly – Encode Ideas

  Francois Brisebois - Oppenheimer