Processa Pharmaceuticals, Inc.
(Nasdaq: PCSA)
November 8, 2022
3Q2022

Processa Pharmaceuticals

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3Q2022 Highlights of Positive Next Generation Capecitabine (NGC) and PCS12852 Trials

- **In the ongoing NGC Phase 1B trial, Processa has successfully identified NGC dosage regimens and 5-Fluorouracil (5-FU) exposures that were well tolerated as well as NGC regimens and 5-FU exposures that had dose-limiting side effects**
- **From the different NGC regimens evaluated, the timeline for the formation of new DPD is approximately 24-72 hours after the PCS6422 dose while NGC potency, based on 5-FU systemic exposure, was increased to 50-times greater than reported for FDA-approved capecitabine**
- **In 2023, Processa plans to initiate an efficacy/safety Phase 2B trial following FDA's Project Optimus Initiative after meeting with the FDA**

- **The PCS12852 Proof-of-Concept Phase 2A trial in gastroparesis patients has been completed with the results showing that the change in gastric emptying rate after 28 days of treatment on 0.5 mg of PCS12852 was statistically better than placebo treatment at a p-value less than 0.10**
- **The change in gastroparesis symptoms for 12852 vs placebo is expected by the end of the year**
- **Processa plans to initiate an efficacy/safety Phase 2B trial in 2023**

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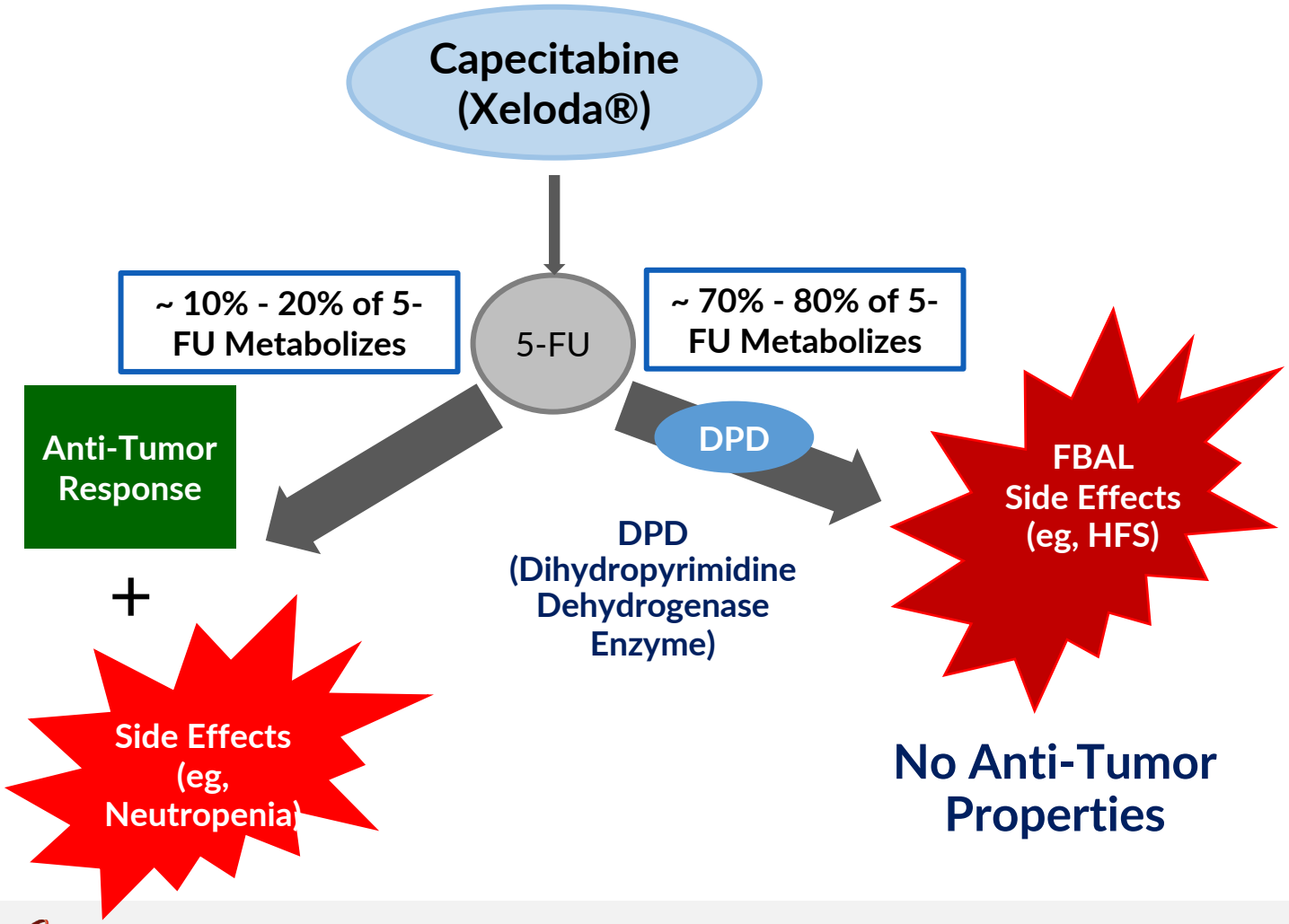
Next Generation Capecitabine (NGC) (Combination Regimens of PCS6422 and Capecitabine)

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

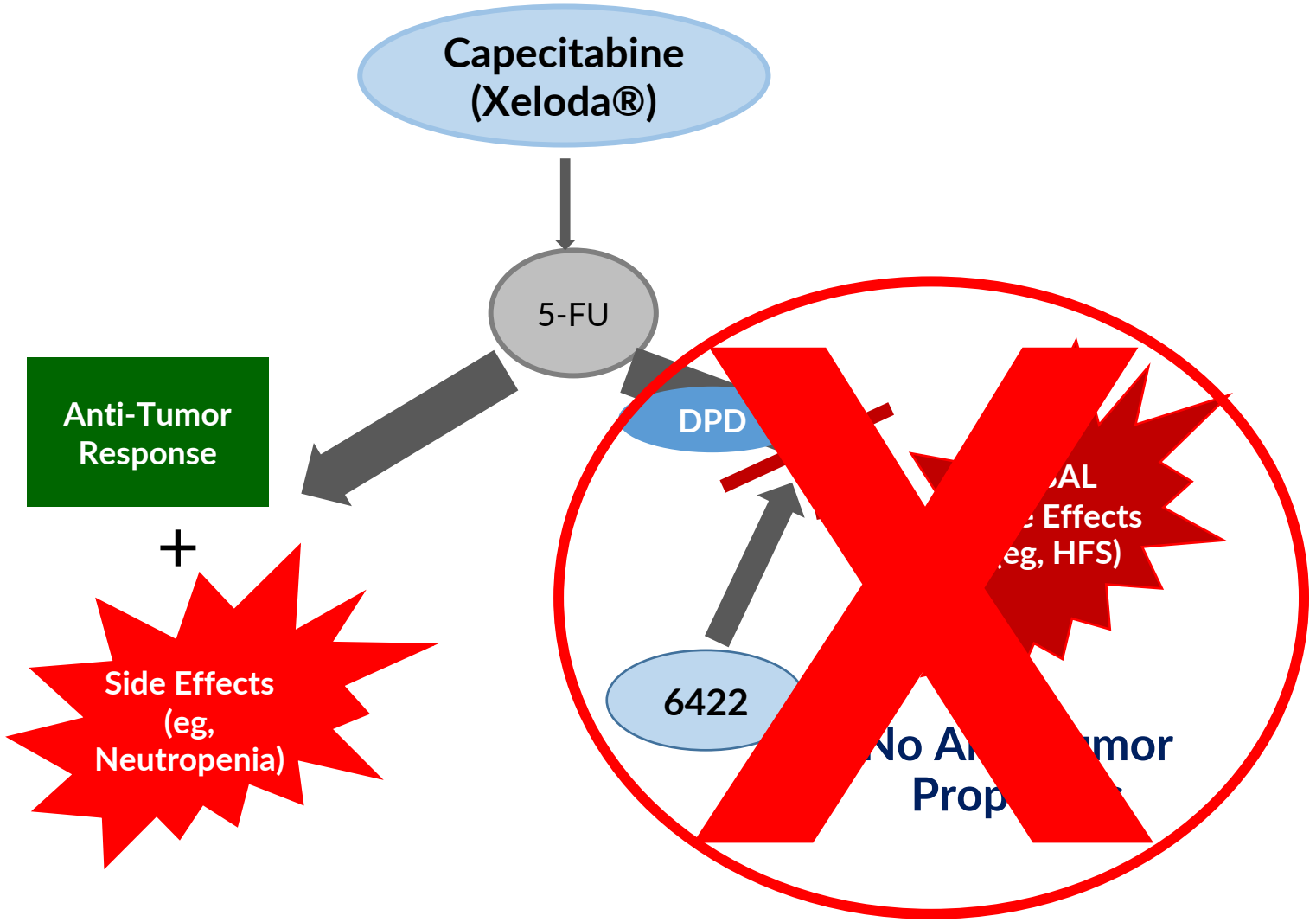
5-Fluorourcail Approved by FDA in 1962 & Capecitabine (Oral Form of 5-Fluorouracil) Approved by FDA in 1998



- **5-Fluorouracil (5-FU) and capecitabine are the most widely used cancer chemotherapeutic agents** for the treatment of a variety of cancers; mainly used as 1st and 2nd line therapy (approx. 750,000 patients in the U.S. and 2 million worldwide)
- **~30% of patients do not respond at all to capecitabine and ~30% are partial responders**
- **Side effects occur from both types of metabolites -** catabolites (no anti-tumor properties) and anabolites (killing both replicating cancer cells and normal cells)
- **25% to 70% of patients have dose-limiting side effects** (either from catabolites, anabolites, or both) requiring dose modifications or discontinuation

Next Generation Capecitabine (NGC): Improved Efficacy & Side Effect Profile

PCS6422 Irreversibly Inhibits DPD (Dihydropyrimidine Dehydrogenase Enzyme)



- **By combining a regimen of PCS6422 with a capecitabine regimen, the 5-FU formed from capecitabine is only metabolized to anabolites** eliminating the adverse events from the catabolites while increasing the potency and potential anti-tumor and replicating cell side effects from the anabolites
- After administration of PCS6422 until new DPD is formed in the patient, 5-FU is only cleared from the body by renal excretion and metabolism to the anabolites within the cells
- **Dosage regimens for NGC** (both the PCS6422 and the capecitabine regimens) **in a Phase 2B trial need to be evaluated to obtain the right balance between efficacy** (anti-tumor response) **and safety** (for example, damage to replicating cells such as neutropenia, mucositis)

Moving Closer to NDA: Phase 1B Trial to Evaluate Safety

- Each Next Generation Capecitabine (NGC) dosage regimen is a combination of a PCS6422 regimen and a separate capecitabine regimen; Example of a single treatment cycle:

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9-14
6422	----	----	----	----	----	----	----	----
----	Cap	Cap	Cap	Cap	Cap	Cap	Cap	----

- **From the different NGC regimens evaluated, the timeline for the formation of new DPD is approximately 24-72 hours after the PCS6422 dose while NGC potency, based on 5-FU systemic exposure, was increased to 50-times greater than reported for FDA-approved capecitabine**

- **Processa has successfully identified NGC dosage regimens and 5-Fluorouracil (5-FU) exposures that were well tolerated as well as NGC regimens and 5-FU exposures that had dose-limiting side effects**

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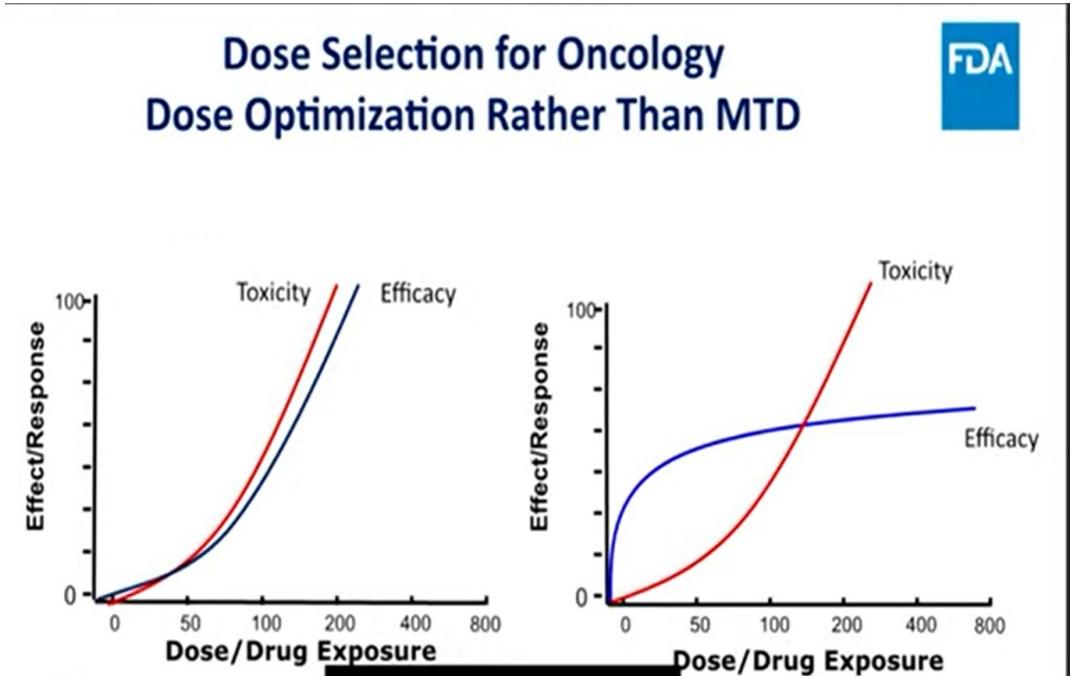
FDA Wants Sponsors to Develop Oncology Drugs Using Principles of Project Optimus



Assumptions with MTD Approach

Assumptions with Project Optimus

Optimizing the Next Generation Capecitabine Regimen Using FDA Project Optimus Initiative

- The approach used for oncology drugs has assumed efficacy and toxicity follow a parallel path; determine the DLT dosing regimen and then use the MTD regimen (the greatest exposure that is still "safe") for the pivotal trial
- The Project Optimus Initiative recommended by the FDA Oncology Division suggests that the MTD approach may not find the optimal efficacy/safety regimen
- The relationship between clinical response and dosage regimen or drug exposure needs to be evaluated to determine if there is a regimen with similar efficacy but significantly fewer and/or less severe side effects
- **Project Optimus Initiative is especially important for combination drug therapy such as NGC where the optimal efficacy/safety balance is dependent on two regimens**

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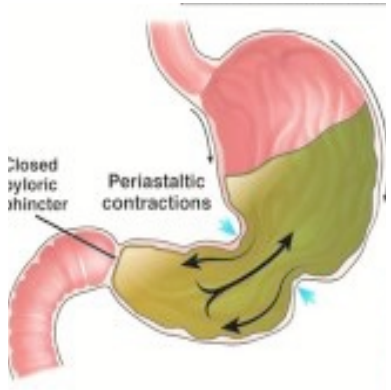
PCS12852

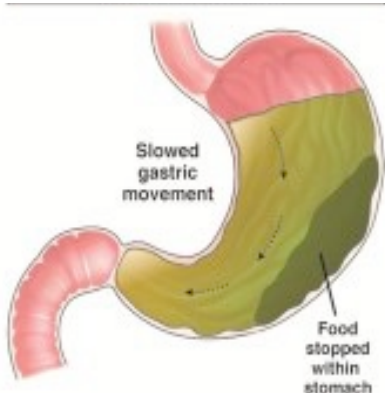
GI Motility Conditions (eg, Gastroparesis)

Gastroparesis

Normal Gastric Emptying



Gastroparesis



<u>Gastroparesis is a condition that affects the normal spontaneous movement of the muscles (motility) in your stomach.</u> The typical symptoms are:

- Feeling full soon after starting a meal
- Feeling full long after eating a meal
- Nausea, Vomiting
- Too much bloating, Too much belching
- Pain in your upper abdomen
- Heartburn
- Poor appetite

- Target Indication:
  - Treatment of moderate to severe gastroparesis
- Target Claims:
  - Improves gastric emptying rate and the symptoms associated with moderate to severe gastroparesis

Treatment of Gastroparesis (> $1.5B Market)

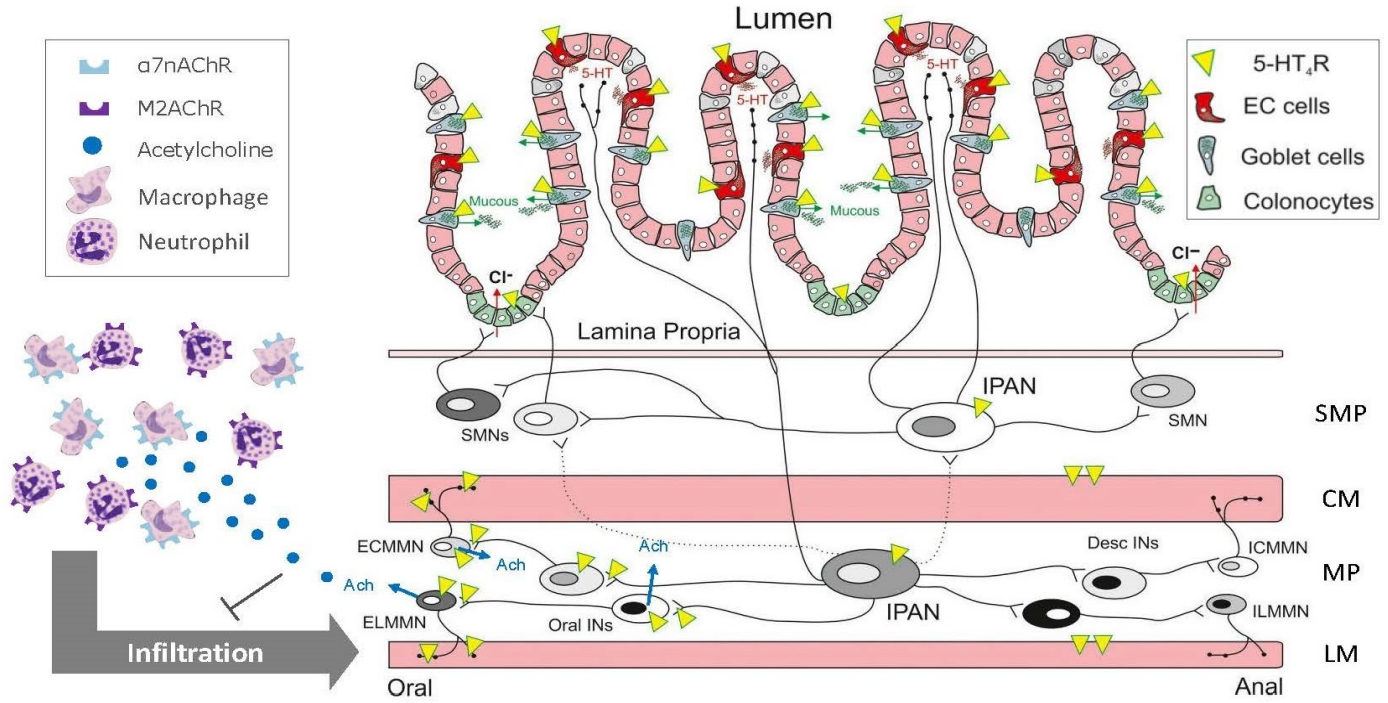
- Existing FDA approved drugs and off-labeled prescribed drugs are mainly used for the treatment of diabetic gastroparesis
- **All these drugs have a poor side effect profile limiting their use**
- Present market size for gastroparesis is estimated to be over $1.0 B in the U.S.

	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

PCS12852: 5-HT4 Receptor Agonist - Wide Range of GI Motility Disorders

Clinically Proven Mechanism of Action

- **<u>Enhancement of both GI motility & secretion</u>** via increased Ach, 5-HT, Cl-and mucus release
- Neural anti-inflammatory effects on post-operative ileus by inhibiting macrophage and neutrophil infiltration
- Wide development potential to treat POGD, gastroparesis, CIC, IBS-c, OIC, and overlap syndrome



Adopted from Gwynne, R.M(2019), Neurogastroenterology & Motility 31(10) and Tsuchida, Y. (2011), Gut 60, 638–647

** Abbreviation*
POGD : postoperative gastrointestinal dysfunction
CIC : chronic idiopathic constipation
IBS-c : irritable bowel syndrome with constipation
OIC : opioid-induced constipation
Ach : acetylcholine
α7nAChR : alpha-7-nicotinic acetylcholine receptor
M2AChR : muscarinic acetylcholine receptor M2
5-HT4R : 5-hydroxytryptamine 4 receptor
EC cell : enterochromaffin cell
CM: circular muscle layer
CMMN: circular muscle motor neuron
E : excitatory
I : inhibitory
IN : interneuron
IPAN : intrinsic primary afferent neuron
LM : longitudinal muscle layer
LMMN : longitudinal muscle motor neuron
MP : myenteric plexus
SMN : secretomotor neuron
SMP : submucosal plexus

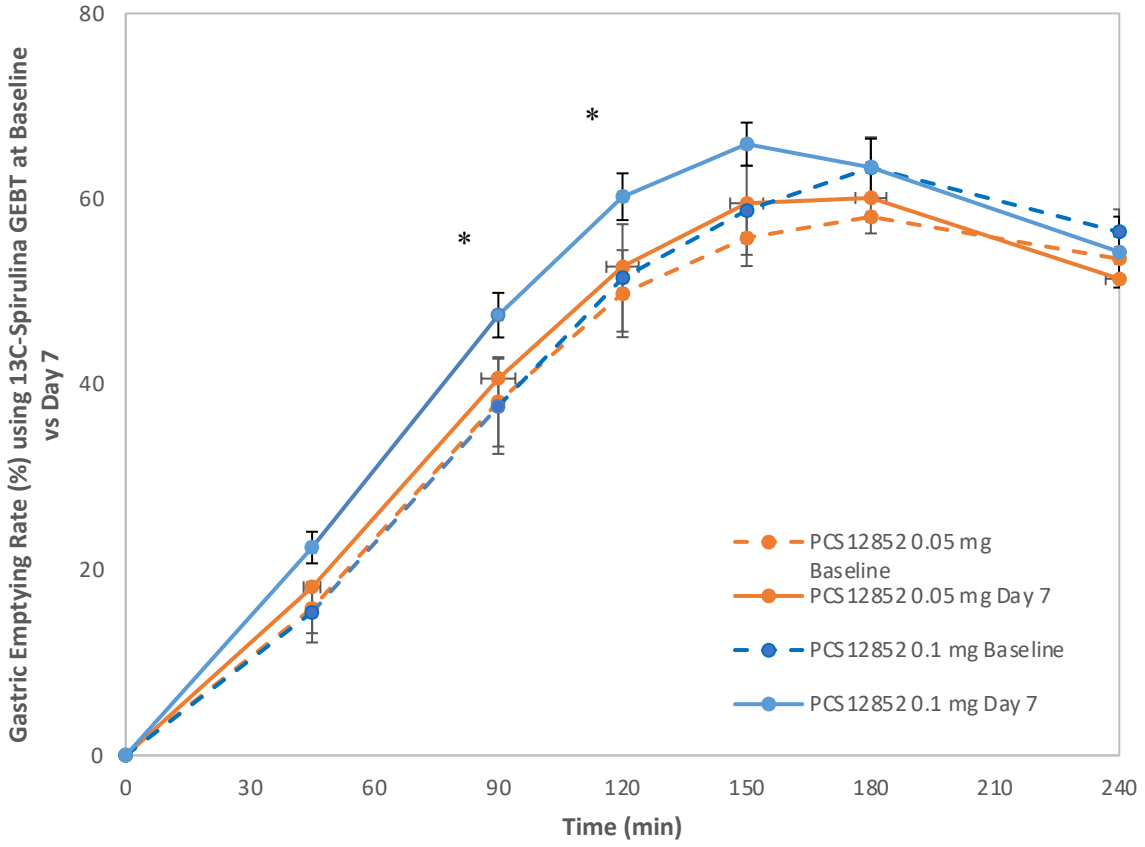
PCS12852 Effect on Gastric Emptying: South Korean and US Trials

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

South Korean Trial

7 – 8 patients per group

Healthy Volunteers (< 3 Bowel Movements per Wk)
or Functional Constipation Patients

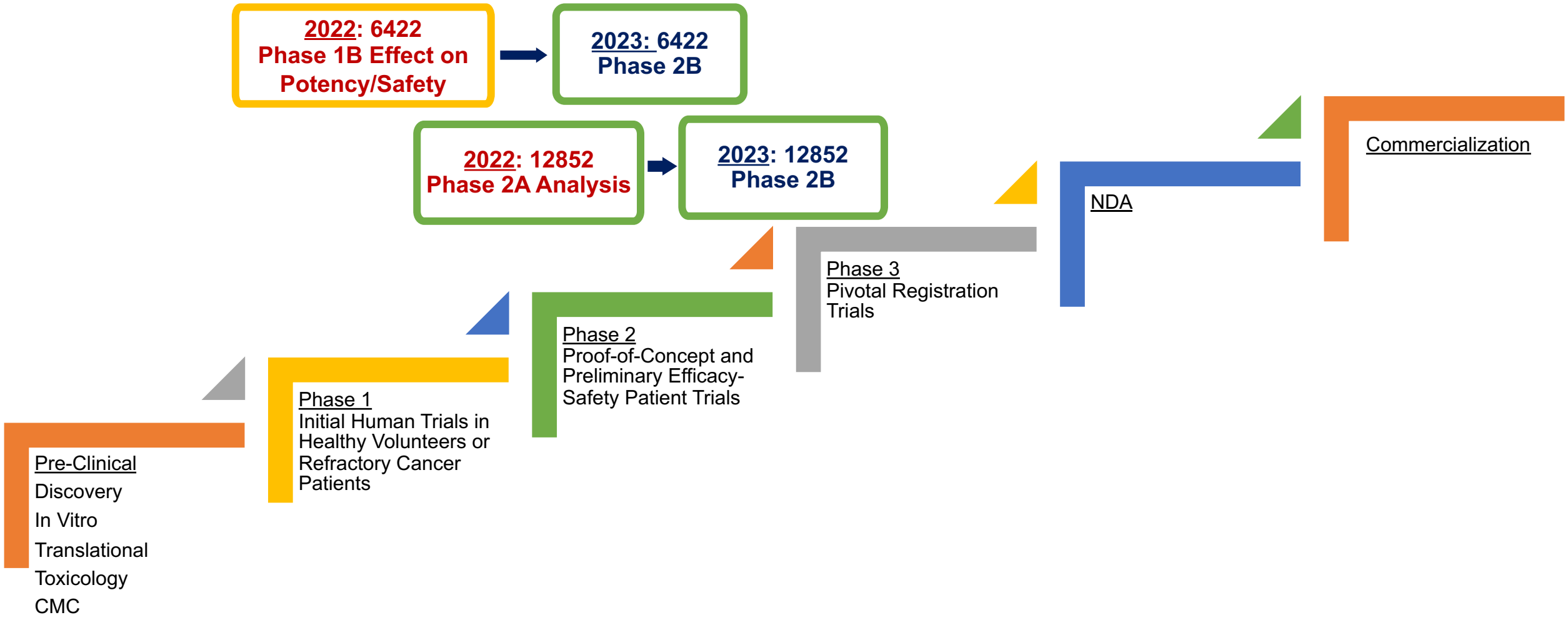


U.S. Phase 2A Proof-of-Concept Trial in Gastroparesis Patients

- Gastric Emptying Breath Test (GEBT) results demonstrated **statistically significant improvement in gastric emptying rate** in patients receiving 0.5 mg of PCS12852 (6 patients) as compared to placebo (8 patients) **at a p < 0.10 level**
- GEBT for 0.1 mg of PCS12852 was not significantly different from the placebo in contrast to what was found in the previous healthy volunteer/constipation patient trial
- **Adverse events were mild to moderate with no clinically significant cardiovascular or serious adverse events**
- Effect on gastroparesis symptoms expected by end of 2022
- **Processa plans to initiate a Phase 2B trial in 2023**

Moving Closer to NDA for 3 Drugs, Each with the Potential of $1B Sales

- **2022 Milestones in Dark Red Text**
- **2023 Study Start-Up in Dark Blue Text**



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Corporate Overview

Our People Lead to Success

- **30 years ago members of the Processa Development Team were involved with 2 FDA contracts where the concept of Regulatory Science was conceived**
- **Development Team members further developed the Processa Regulatory Science Approach while obtaining > 30 FDA approvals for indications across almost every FDA division**
- **Management Team involved with billion dollar exits (Questcor - $5.7 B & Gentium - $1.0 B)**

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 Independent 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

Approach to Building the Processa 5 Drug Pipeline
Drug Development Company Not a Discovery Company

- Clear and obvious **patient need to improve quality-of-life and/or survival**
- **Favorable competitive** dynamics

- **Evidence of clinical efficacy** in targeted medical condition
- **Higher** probability of **successful development**

- **Design development program and clinical trials** to improve the likelihood of an FDA approvable Benefit-Risk profile
- **Increase the probability of approval while decreasing the time and cost to approval**

- **Leverage** considerable **prior investments** before licensing (tox, CMC, etc.)
- **Conduct efficient development** program and clinical trial design

- **Intelligently monetize assets**

Processa Pharmaceuticals, Inc (NASDAQ: PCSA) Differentiated Business Model

- Processa has a **capital-efficient approach** based on very low overhead, disciplined licensing, and intelligent/efficient development, all leading to a potentially high ROI (6 C-suite to receive < $600,000 total cash salary in 2022)
  - **Management and Board investment > $6 M**
  - **C-Suite exchanged approx. $1.25 M of salary for PCSA shares in 2022**
- Processa has **enough cash to complete the 3 ongoing clinical trials in 3 separate $1B markets** with key value-added milestones occurring in 2022 and 2023 while moving closer to NDA
  - **Next Generation Capecitabine (PCS6422+capecitabine) Phase 1B** trial in GI cancer
  - **PCS12852 Phase 2A** trial in gastroparesis
  - **PCS499 Phase 2B trial** in ulcerative necrobiosis lipoidica
- Three cancer drugs in the 5 drug pipeline
  - **Next Generation Capecitabine (PCS6422+capecitabine)** Phase 1B trial in **GI cancer**
  - **PCS3117 (similar to Gemcitabine) Orphan Designation and IND for pancreatic cancer;** Phase 2B study design underway with the possibility of biomarkers
  - **PCS11T (next generation irinotecan)** to begin CMC and IND enabling tox studies for **small cell lung cancer**

Pipeline of Five Drugs Each with $1B Market Opportunity

Drug	Disease Target	Market
Next Generation Capecitabine (PCS6422) Phase 1B	Metastatic Colorectal Cancer and Other Types of Cancer	U.S. Incidence of Metastatic Colorectal Cancer : > 60K Pts U.S. Max Ann. Sales mCRC: $500 M – $1.0 B Global Max Ann. Sales mCRC: > $1.0 B
PCS12852 Phase 2A	Moderate/Severe Gastroparesis and Other GI Motility Conditions	U.S. Prevalence of Mod/Sev Gastroparesis: 2M - 5M Pts U.S. Max Ann. Sales Mod/Sev Gastroparesis: > $1.0 B
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica (uNL) and other Rare Diseases	U.S. Prevalence of uNL: 10K - 50K Pts U.S. Max Ann. Sales uNL: $500 M - $1.0 B Global Max Sales uNL: > $1.0 B
PCS3117 Phase 2B	Pancreatic, Other Cancers	PCS3117 market would target patients who receive Gemcitabine (both Gemcitabine resistant and non-resistant patients)
PCS11T Pre-IND	SC Lung, Other Cancers	PCS11T market would target patients who receive Irinotecan (PCS11T potentially has a better side effect profile)

Moving Closer to NDA for 3 Drugs, Each with the Potential of $1B Sales

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