Processa Pharmaceuticals

Clinical Pipeline Update
November 2021

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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 and Development Team with Track Record of Success**
- **Drug Development Regulatory Science Approach (RSA) Improves Probability of Success for Investors & Patients**
- **Capital Efficient with a Tightly Controlled Burn Rate (G&A < $4M per year with 16 Employees)**
- **Key Accomplishments in 3Q'21**
  - Next Generation Capecitabine (combination of PCS6422 and capecitabine; formerly identified as PCS6422): PCS6422 alters the metabolism of 5-FU but not as long as expected; Next Generation Capecitabine is more potent than expected when DPD enzyme inhibited
  - PCS499: 3 patients enrolled with 2 more potential patients in next month
  - PCS12852: Safe to Proceed Letter for IND
- **High Value Milestones Completed in the Next 15 Months**
  - Next Generation Capecitabine: selection of 6422 regimen(s) based on timeline of DPD inhibition and de novo formation evaluated; determine capecitabine MTD
  - PCS499: interim analysis and final analysis
  - PCS12852: Phase 2A trial conduct completed
  - Regulatory submissions to expedite development and approval (e.g., Fast-Track, Breakthrough Therapy)
- **U.S. and Non-U.S. Biotech Companies Contacting us about Acquiring our Drugs**

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 2021-2022 & 4 NDAs in 2025 - 2028

Drug	Disease Target	Nonclin	Phase 1	Phase 2	Phase 3	Status	2021-2022 Milestones	2023 – 2028 Milestones
PCS499 Phase 2B	Ulcerative Necrobiosis Lipoidica			*		3 Patients Dosed; 1 Patient in Screening, All Clinical Sites Recruiting	Interim Analysis Mid-2022; Final Analysis 2H'22	FPI Phase 3 2023; NDA 2025-2026
PCS12852 Phase 2A	Gastroparesis, Constipation Disorders			*		IND Safe-to-Proceed; Initiating Trial Sites	FPI Phase 2A 1H'22; Trial Conduct Completed 2H'22	FPI Phase 3 2025-2026, NDA 2027-2028
PCS3117 Phase 2B	Pancreatic, Non-Small Cell Lung Cancer			*		Biomarker Assay Lab Protocols Being Prepared	Complete Biomarker Assays 1H'22; FPI Phase 2B 2H'22	FPI Phase 3 2023 – 2024; NDA 2026-2027
Next Generation Capecitabine Phase 1B (PCS6422)	Metastatic Colorectal, Breast Cancer		*			Cohort 1&2 no DLTs; 6422 Alters 5-FU Metabolism for 1-2 days, not 7 days; Modifying Protocol to Monitor DPD	Restart Phase 1B Mid-1H'22; 6422 Regimen and Capecitabine MTD Determined 2H'22	FPI Phase 2B/3 2023 – 2024; NDA 2027 - 2028
PCS11T Pre-IND	Small Cell Lung, Colorectal Cancer					CMOs and CROs Being Evaluated	Complete IND Enabling Studies	Phase 1B IND Submission 1H'23

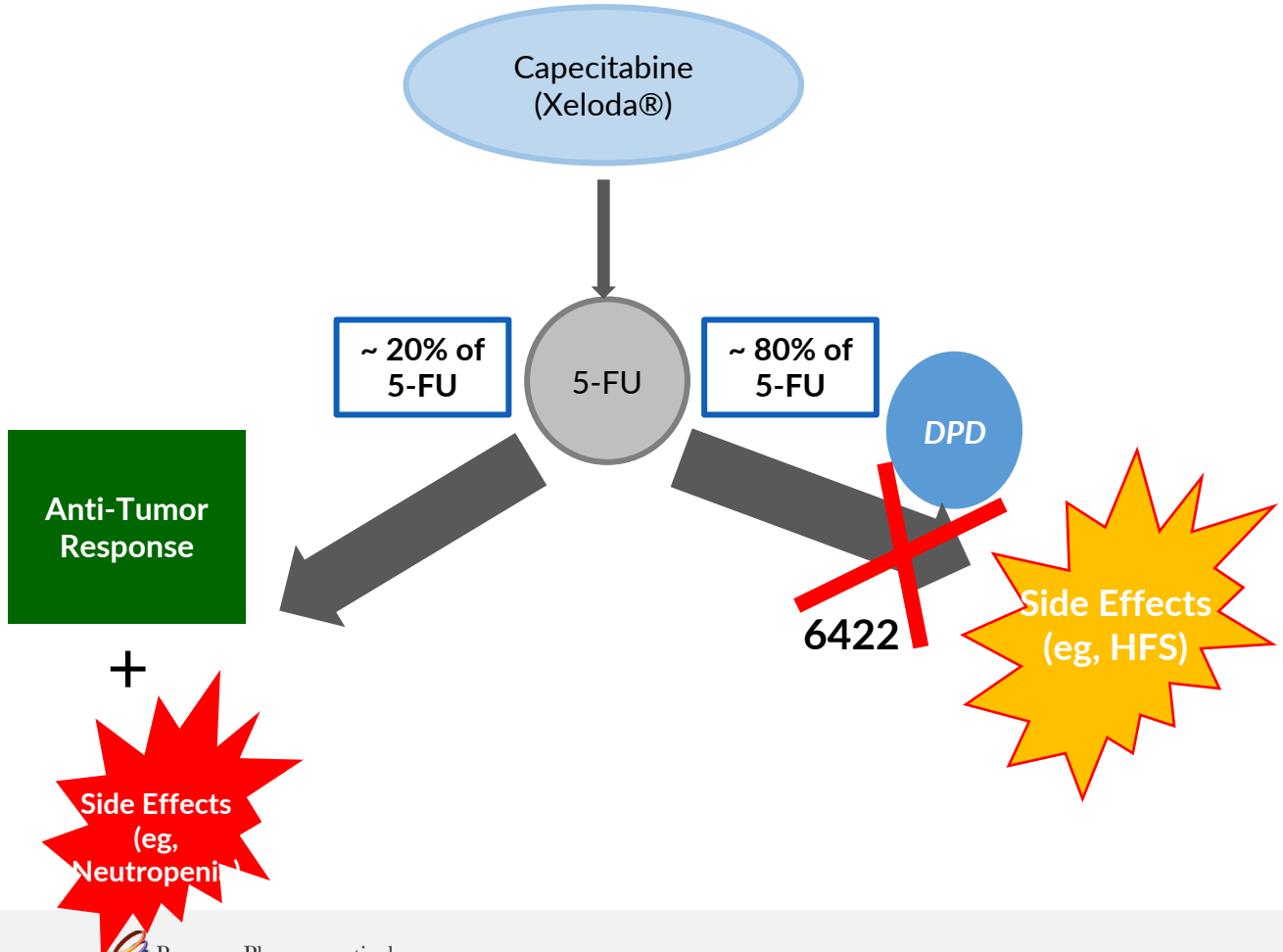
* Cleared by FDA for Clinical Trial

Blue - Use of Existing Cash

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

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

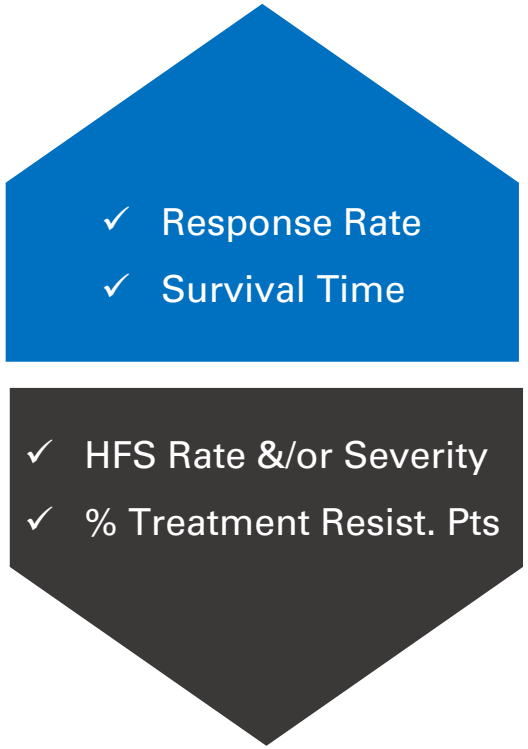
When PCS6422 Irreversibly Inhibits DPD, Next Generation Capecitabine Should be More Potent Than FDA Approved Capecitabine



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
- Improved metabolism profile and increased potency did **not exist 7 days** after PCS6422 administration
- **Postponed further enrollment** of patients in trial

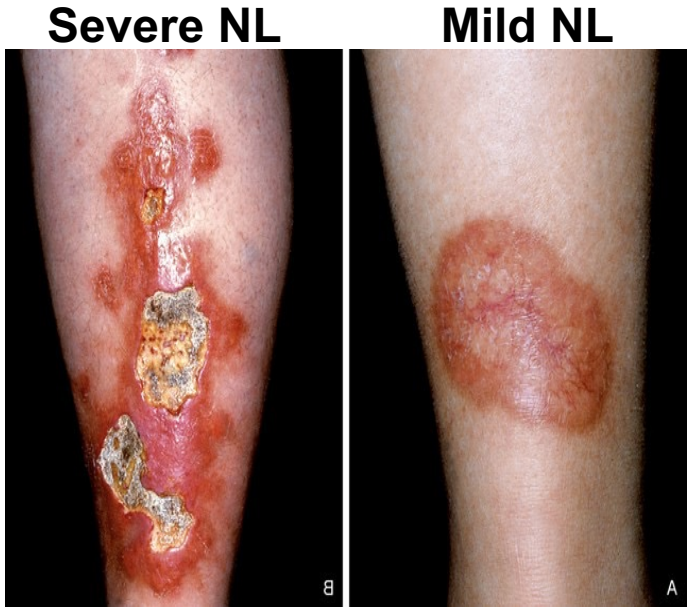
Next Generation Capecitabine: Next Steps and "Audible" Call by Processa



- Since 6422 irreversibly inhibits DPD, metabolism to FBAL after 6422 administration occurs from any DPD not inhibited by 6422 and the formation of new DPD molecules
- **Timeline of DPD inhibition and de novo formation needs to be further evaluated** in order to identify 6422 regimens which will inhibit DPD throughout capecitabine dosing
- Present **Phase 1B protocol is being modified** with the plan to discuss the modifications with FDA
- Processa expects to **restart enrollment of patients mid-1H'22** and define the Next Generation Capecitabine regimens for both 6422 and capecitabine by end of 2022
- **Evaluating other regulatory submissions** to expedite development and approval (e.g., Fast-Track, Breakthrough Therapy)
- **Overall timeline** for initiation of Phase 2B/3 trial (2023-2024) and NDA submission (2027-2028) are **not expected to change**; additional DPD information may offer a personalized therapeutic drug monitoring approach to treating each cancer patient

PCS499: First Drug to Treat Ulcerative Necrobiosis Lipoidica (uNL) ($1B Market)

- Skin and tissue below the skin becomes necrotic; can last from months to years with complications such as infections, amputation, and cancer
- 30% of NL patients have painful ulcers occurring naturally or from contact trauma to the lesion; **22,000 – 65,000 uNL patients in U.S**.
- **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**
- Drugs have been **used off-label with mixed success (e.g., pentoxifylline (PTX))** - side effect profile, limited efficacy
- **1.8 gm/d of PCS499 (deuterated analog of PTX metabolite) has better safety profile than 1.2 gm of PTX** in animal tox studies and Phase 1 healthy human volunteer studies
- In PCS499 Phase 2A trial, the **ulcers on the only 2 patients with ulcers completely healed and contact ulcers formed during the study healed within 1 month**



PCS499: Status, Next Steps

- In uNL Phase 2B randomized, placebo-controlled trial, **3 patients have enrolled, 1 patient is being screened, and 1 patient failed screening**; a total of 20 patients to be enrolled
- The critical findings in this study will be evaluating both the placebo and 499 response rate
  - If the placebo response rate (response defined as complete wound closure) is 5% or less as many believe and PCS499 response rate is 50%, < 30 patients will be required in the pivotal trial
  - If the response rates are 5% or less and 30%, 70 patients will be required in the pivotal trial
- Expect to perform **interim analysis of Phase 2B trial mid-2022 and final analysis 2H'22**
- **Evaluating other regulatory submissions to expedite development and approval** (e.g., Fast-Track, Breakthrough Therapy)
- FPI Phase 3 with Special Protocol Assessment expected 2023
- NDA Submission expected 2025-2026 with 1 Phase 3 trial

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**

- **Received Study May Proceed Letter** from FDA for Phase 2A trial
- 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 has started
- **FPI for Phase 2A expected 1H'22 with completion of study conduct 2H'22**
- Final analysis of Phase 2A expected 2H'22 – 1H'23
- Primary endpoints in Phase 2B and Phase 3 trials will be based on symptoms

What's Expected Over the Next 6-9 Months?

- Next Generation Capecitabine (Combination of PCS6422 and Capecitabine; Formerly Identified as PCS6422 Program)
  - **Expect to restart enrollment of Phase 1B trial mid-1H'22 with the goal to define the Next Generation Capecitabine regimens of both 6422 and capecitabine by the end of 2022**
  - **Modifying the Phase 1B trial** to evaluate the timeline of DPD inhibition and de novo formation in order to determine 6422 regimens needed to inhibit DPD throughout capecitabine dosing
  - Interact with FDA on modifications of Phase 1B trial before restarting trial
- PCS499
  - **Complete enrollment of patients for the interim analysis of 499**
- PCS12852
  - **Begin enrollment of Phase 2A trial**
- Regulatory Submissions to Expedite Development and Approval (e.g., Fast-Track, Breakthrough Therapy)

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Our People Lead to Success

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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
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Founding and Managing Partner of GLTJ Pioneer Capital

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Former CEO of Gentium
Chairman of the Board of Fennec Pharm.