Processa Pharmaceuticals

CLINICAL PIPELINE UPDATE
NOVEMBER 2020

Disclaimer: Forward Looking Statements

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Processa Pharmaceuticals (NASDAQ: PCSA)

- **Differentiated Business Model Applying the Processa Regulatory Science Platform to Drug Development**
- **Capital Efficient – Very Low Overhead, Disciplined Licensing, Intelligent Development, Potentially High ROI**
- **Focus on Licensing/Acquiring De-Risked, Under-Appreciated Assets with Demonstrated Efficacy & Higher Probability of Successful Development**
- **Management and Development Team with Track Record of Obtaining FDA Approvals & Creating Significant Shareholder Value**
- **Raised $19.2 M in NASDAQ Uplist to Move Forward with Three Clinical Trials for Three Separate $1B Markets - Key Value Added Milestones Over the next 12 - 18 Months**

Regulatory Science Platform

- ✓ **Processa Team Taught FDA Reviewers**
- ✓ **Received FDA Contracts to Conduct Scientific Studies to Support FDA Regulatory Guidances**
- ✓ **30+ FDA Drugs Approved**
- ✓ **100+ FDA Meetings**

Successful Exit

QUESTCOR® PHARMACEUTICALS, INC.

Processa's Differentiated Development Approach

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

DEVELOP NOT DISCOVER

REGULATORY SCIENCE PLATFORM

High Unmet Medical Need	+	Efficacy Evidence	+	Regulatory Science	+	Capital Efficiency	=	Potentially High ROI
▪ Clear and obvious patient need ▪ Favorable competitive dynamics		▪ Direct proof of concept or other proof of principal ▪ De-risking development, higher probability of successful development		▪ Optimize trial design (Trifecta: ↓risk, ↓cost, ↓time to approval) ▪ Anticipate what FDA requires to assist in discussions on IND enabling studies, clinical trials, and approval		▪ Leverage considerable investments prior to licensing (tox, CMC etc.) ▪ Efficient clinical trials and development program		▪ Intelligently monetize and partner assets

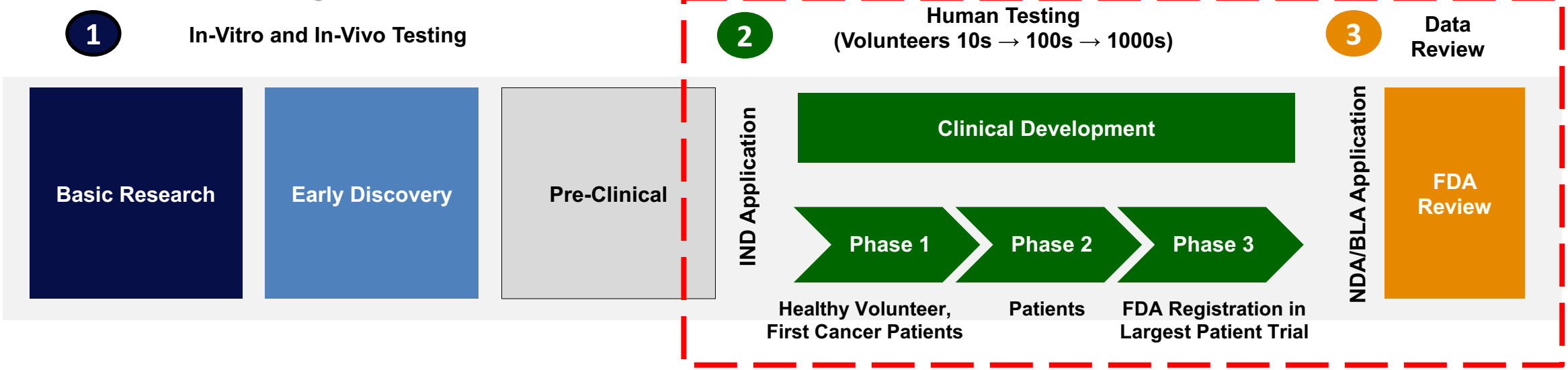
Typical Biotech Company Goes Through Stages 1 to 3

Substantial R&D Expenditures With High Risk / High Reward Characteristics

High Risk, Often Unproven Targets, Time Consuming, Expensive

Processa Approach

To Improve the Risk/Reward for Commercialization Processa Applies Their Regulatory Science Platform from IND Enabling Toxicology, Drug Manufacturing Studies Through FDA Approval



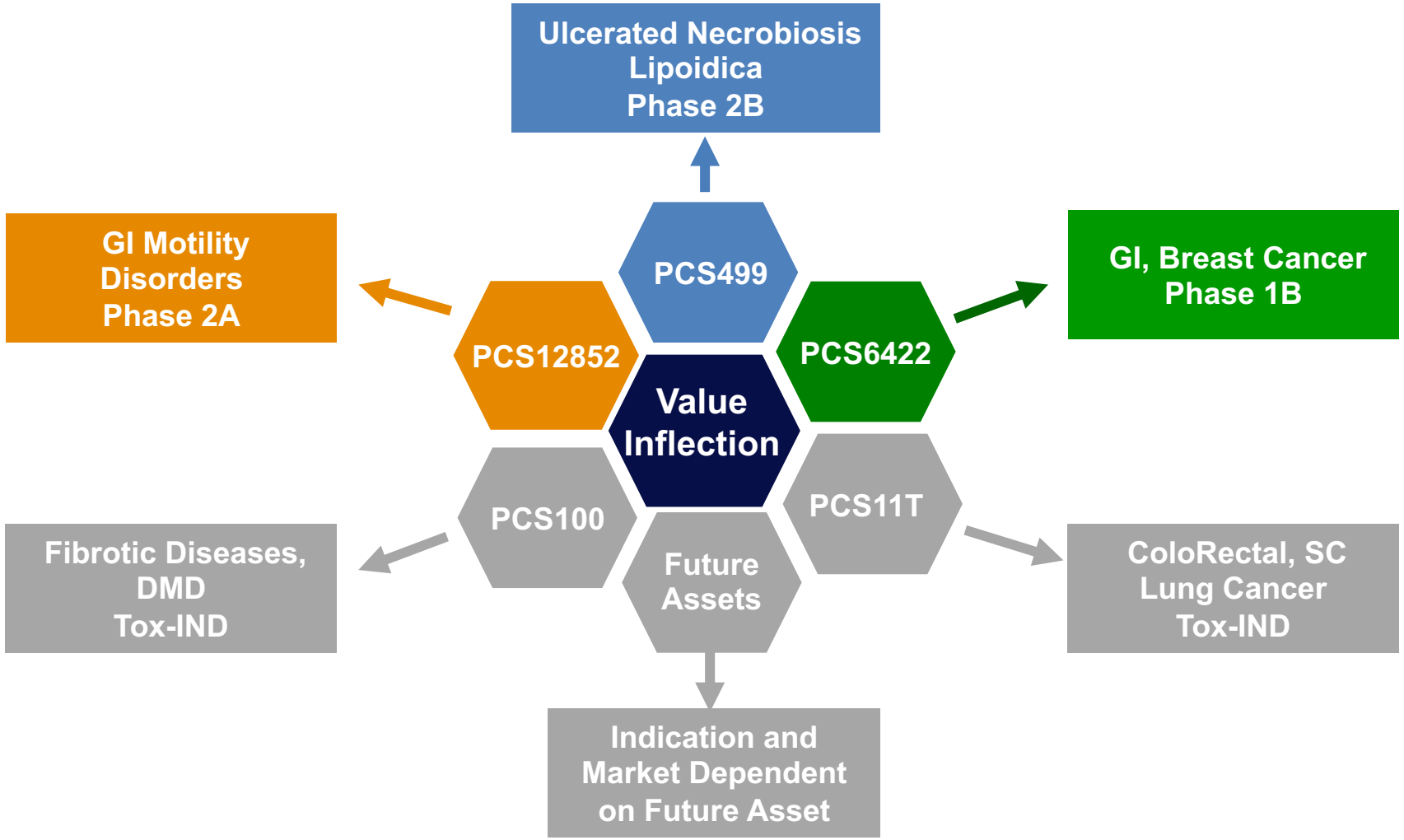
Each Positive Clinical Study Moving from Phase 1 to Phase 2 to Phase 3 Increases the Probability of FDA Approval and Increases the Value of the Drug

Processa Pipeline – Multiple Opportunities For Success

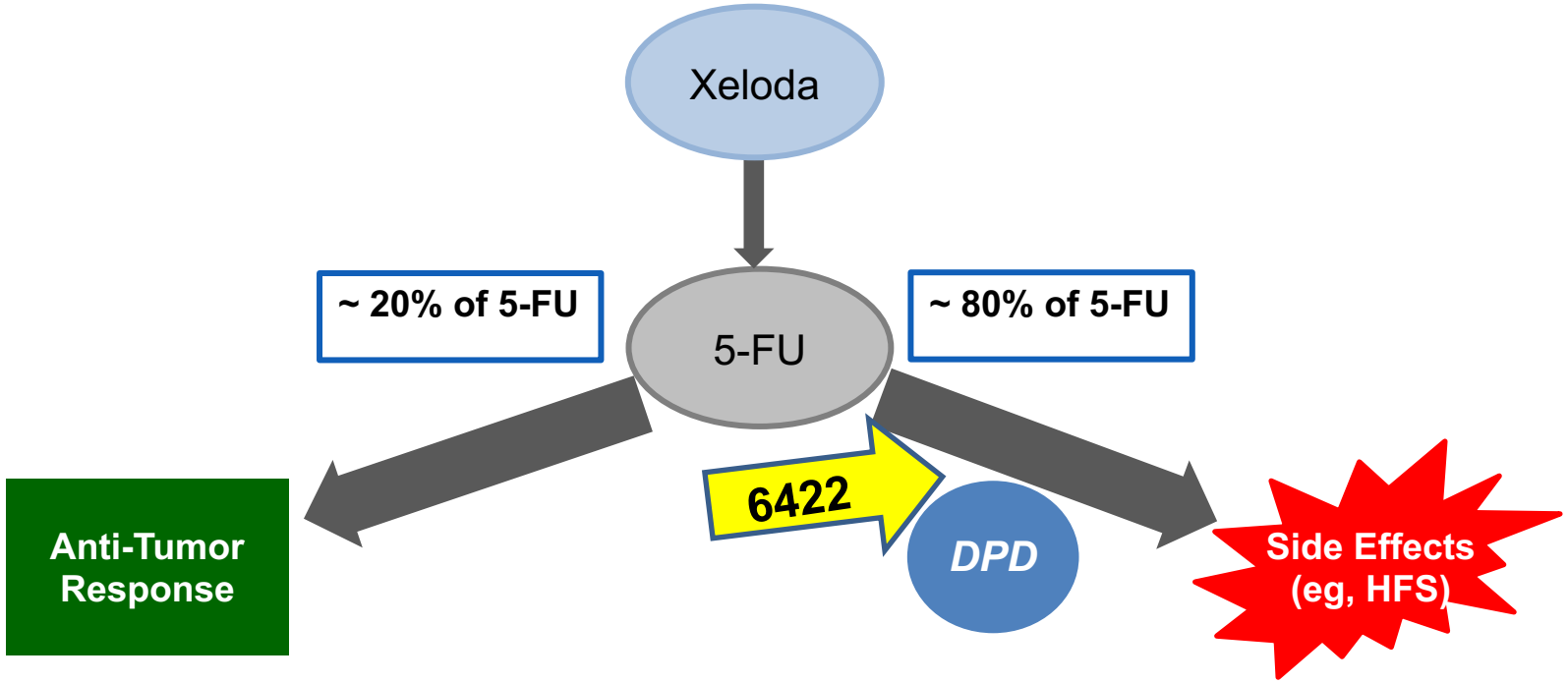
Use Studies of Prior Companies and Hundreds of Millions of Dollars Invested

Pipeline

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓



PCS6422 Irreversibly Inhibits Dihydropyrimidine Dehydrogenase (DPD) Enzyme



Xeloda® (Capecitabine) Converts to 5-FU in the body:

- **~ 20% of 5-FU Metabolizes to Molecules with Anti-Tumor Activity**
- **~80% of 5-FU Metabolizes to Molecules that Cause Dose Limiting Side Effects**

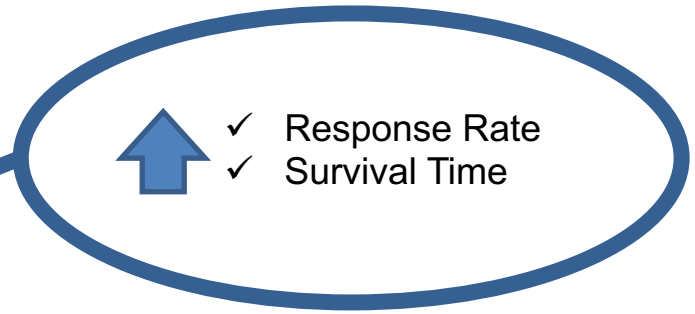
6422 Inhibits DPD Allowing Two Ways to Win

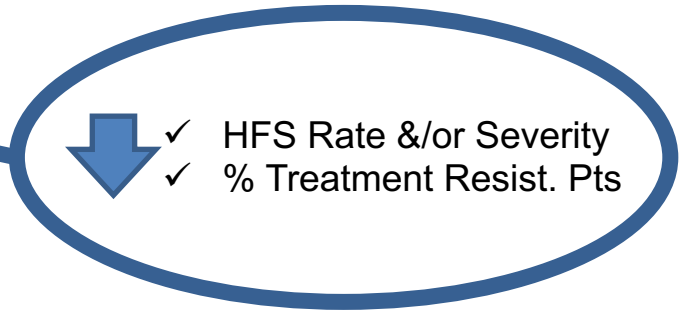
1. **Lower Side Effects With Lower 5-FU Metabolite FBAL– Potentially Improve QOL & Reduce Treatment Discontinuations**
2. **Improve Capecitabine Efficacy – Potentially Increase Response Rate and/or Lower Capecitabine Dose**

PCS6422 – Xeloda Combination Target Population: Cancer Patients Who Need a Better & Safer Cancer Treatment Option - Multiple $1B

Xeloda® (Capecitabine) and 5-FU

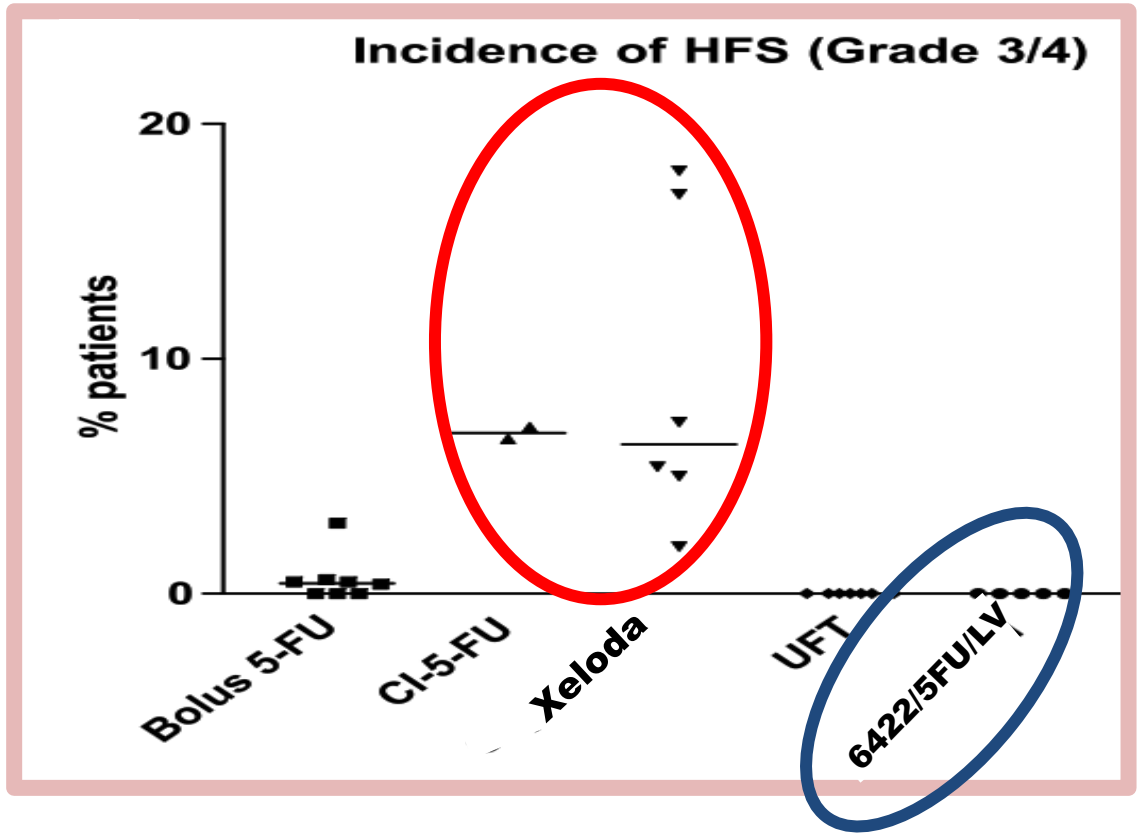
- Xeloda and 5-FU are the cornerstones of cancer chemotherapy with millions of patients treated annually
- Widely used as 1st line therapy in
  - Colorectal cancer; > 145,000 new patients/yr U.S., > 1.8 M total patients with colorectal cancer worldwide
  - Breast cancer; > 275,000 new patients/yr U.S., > 2.0 M total patients with breast cancer worldwide
- **Resistant -** No 5-yr Progression Free Survival: ~ 25-35% of patients treated
- Side Effects: ~50% - 70% of patients develop Hand-Foot syndrome (HFS) which often requires dose interruptions, adjustments, discontinuation





PCS6422 Significantly Reduces HFS

Patients Receiving 6422 and Oral 5-FU Had Lower Incidence of HFS (Particularly Grade 3/4) Compared to Xeloda or i.v. 5-FU Because of Significantly Less Toxic 5-FU Metabolites (F-BAL)



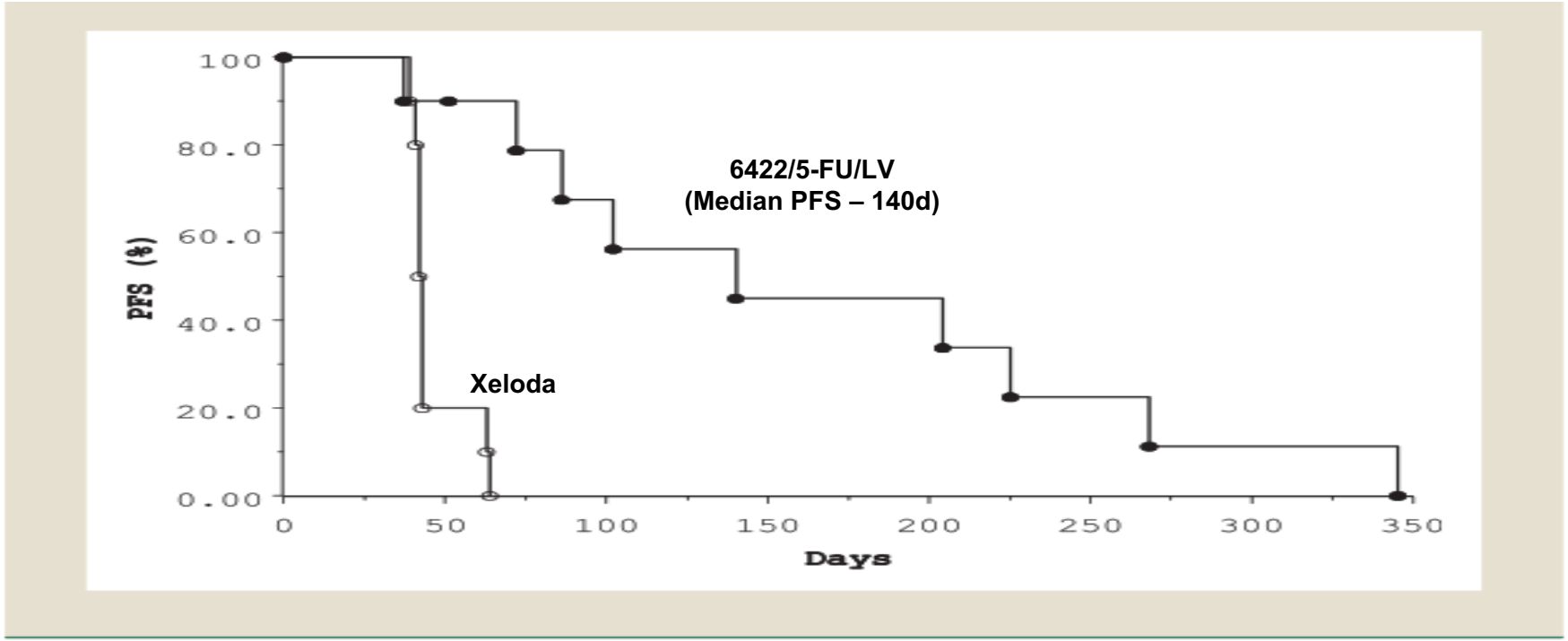
Hand–foot syndrome (HFS) is the most common adverse effect of Xeloda and 5-FU, with an incidence of 50–70%, and its occurrence can lead to dose interruptions, adjustments, discontinuation

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

PCS6422 Effect on 5-FU Efficacy Depends on Dose Amount and Time of Dosing Relative to 5-FU Administration

Improve Efficacy with 6422:

Lower Dose of 6422 Administered Hours Before 5-FU/LV in Xeloda 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

Positive 6422-Xeloda Phase 1B Trial Increases Probability of FDA Approval by Providing Data to Help Design Pivotal Phase 2/3 Trial

PCS6422

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓
- 5-FU Experience ✓

History

- ✓ Completed Pharmacology, Toxicology, CMC
- ✓ 6422 + 5-FU Phase 3 Clinical Trials – Efficacy of 6422 + 5-FU not Demonstrated Due to Sub-Optimal Scheduling and Dosing
- ✓ Phase 2 POC Trial with a More Rational 6422 + 5FU Dosing Regimen-Scheduling Provided Preliminary Evidence of Efficacy

Phase 1B Trial

- ✓ IND Cleared by FDA for Phase 1B 6422 + Xeloda Maximum Tolerated Dose Finding Trial with New Dosing Regimen-Schedule
- ❑ **Increase Exclusivity with Possible New Patents**

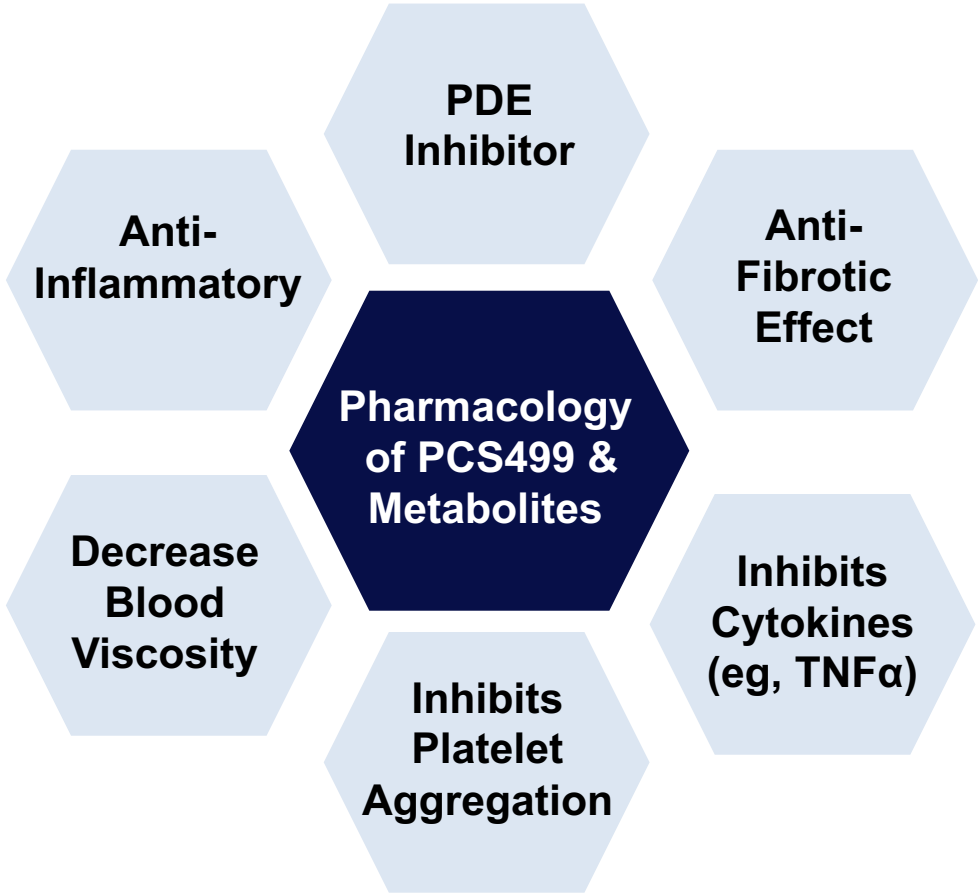
Timeline

- ❑ **Phase 1B Initiate Sites, Begin Patient Dosing 4Q'20-1H'21**
- ❑ **Phase 1B Interim Cohort Results Begin 3Q'21**
- ❑ **Phase 1B Final Report 2H'22**
- ❑ **Phase 2/3 Trial 1H'23**

PCS499: Diverse Pharmacological Properties

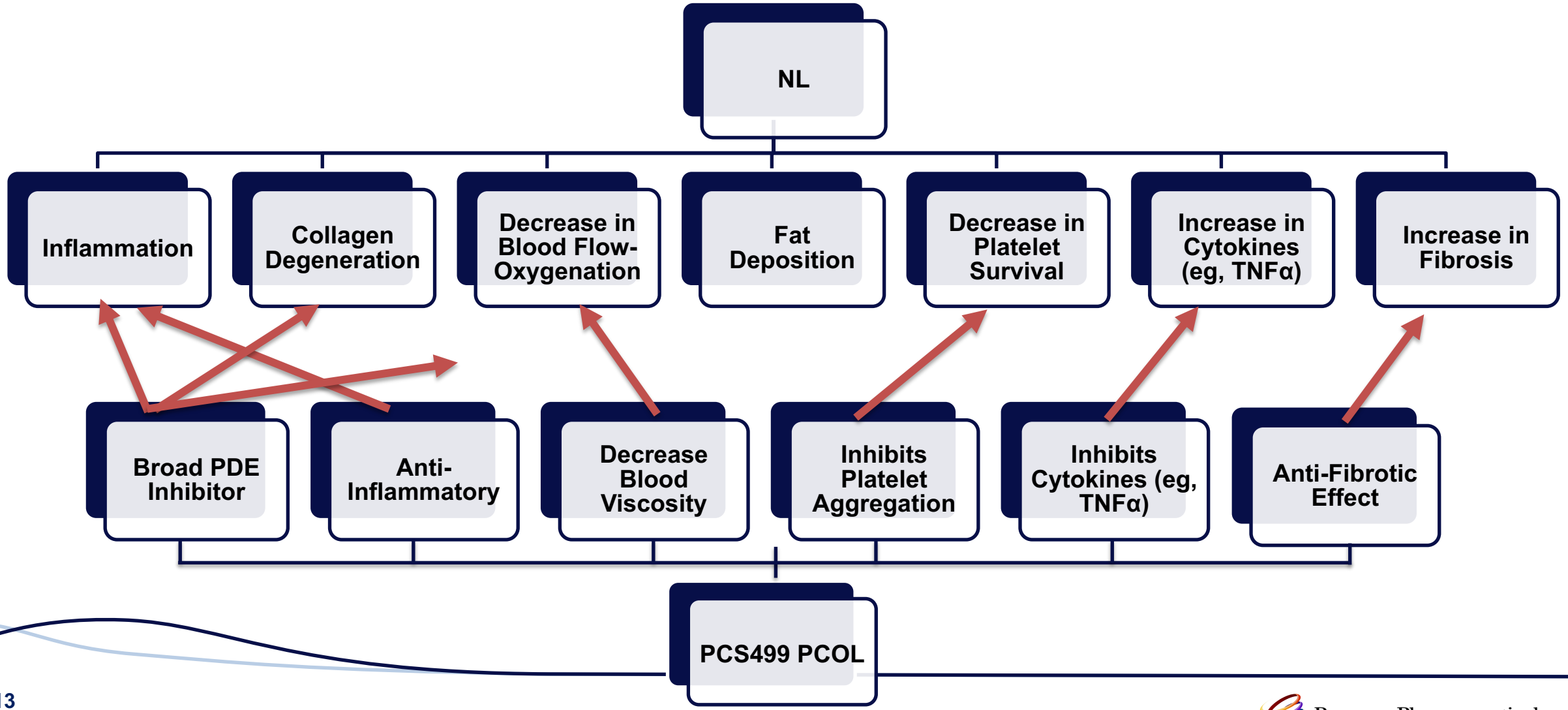
Deuterated Analog of Major Active Metabolite of Pentoxifylline (PTX), FDA Approved for Claudication

- 499 metabolizes qualitatively to **same** active moieties as PTX but **quantitatively has different amounts of these metabolites**
- PTX has dose limiting side effects which can limit its use; preclinical and clinical evidence shows that **499 has less side effects than PTX allowing higher doses to be administered**
- PTX has been shown to **successfully treat some patients with a rare disease called Necrobiosis Lipoidica (NL)** and might be able to successfully treat more if a higher dose could be administered without dose limiting side effects
- Identified 499 **diverse pharmacology** could be ideal to treat NL with its **diverse pathophysiology**



PCS499: Necrobiosis Lipoidica (NL) Diverse Pathophysiology Requires Diverse Pharmacology

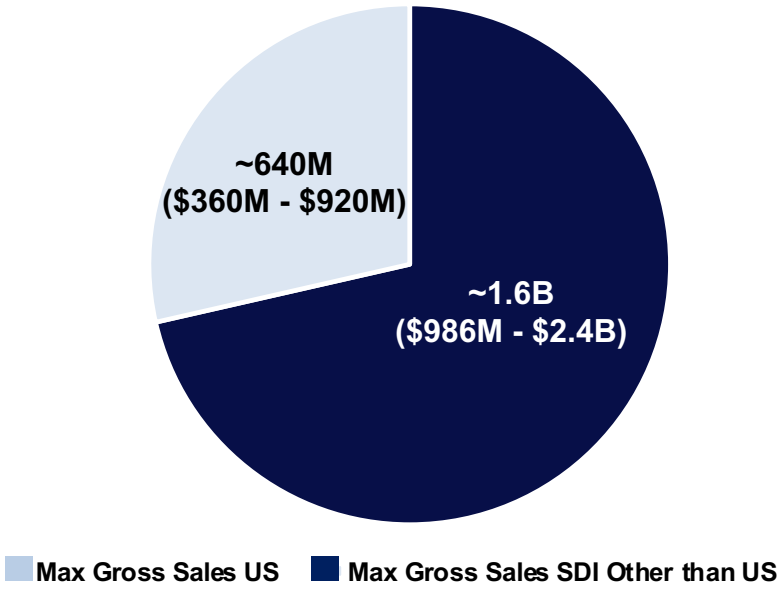
PTX Successfully Treats Some NL Patients who can Tolerate the Drug



PCS499 Target Population: Ulcerative Necrobiosis Lipoidica (uNL) Patients Have No Treatment Options - $1B Market

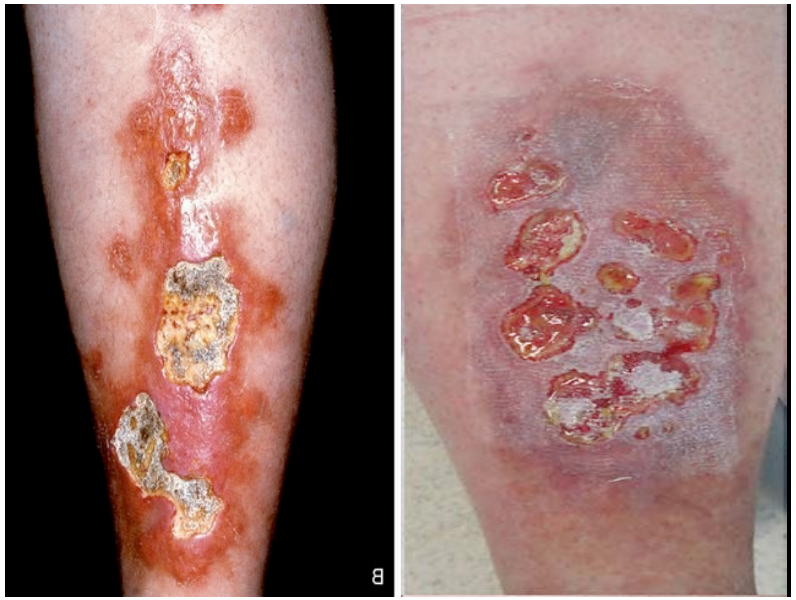
PCS499 has 7-year exclusivity with Orphan Designation for NL

Ulcerative Necrobiosis Lipoidica (uNL)
Max Gross Sales



- **22,000 – 55,000 uNL Patients in US**
- **150,000 – 400,000 uNL Patients Worldwide**

Ulcerative NL

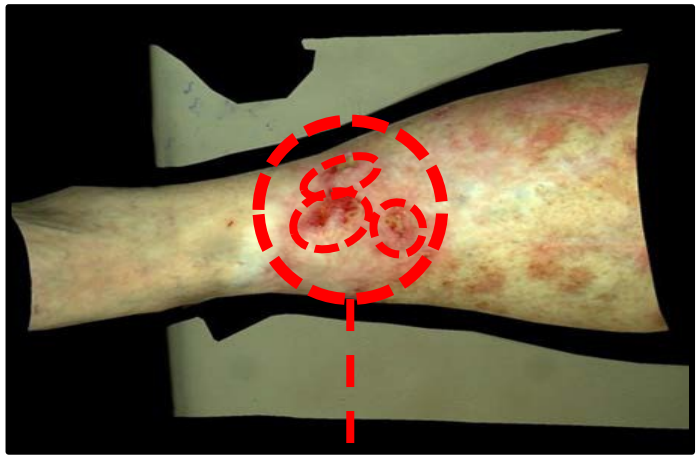


- **Clinical Presentation**: Skin, tissue below skin becomes necrotic with complications, rare disease, no approved FDA Drugs, no drugs in development
- **Target Patient Population**: 60% of NL patients are diabetic but NL is not dependent on glucose control and not the same as diabetic foot ulcers
- **Natural Healing of Ulcers**: Ulcer closure rate is significantly less than 10% of the patients over the first 1-2 years after onset

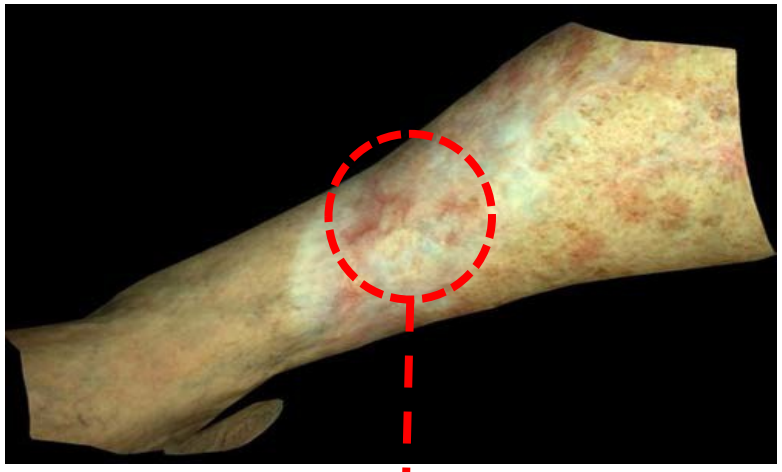
Source: Muller SA, et al. Arch Dermatol. 1966; Jockenhöfer F, et al, J Dtsch Dermatol Ges. 2016; Company

PCS499 Well Tolerated and Completely Closes Ulcers in a Small NL Patient Study

- **Evidence of PTX Efficacy in Ulcerated NL Patients:** Number of case reports that PTX can close ulcers in NL patients if they can tolerate the highest dose of PTX, KOLs would like a more potent PTX
- **Tolerance of PCS499 Better than PTX:** PCS499 is well tolerated at dose greater than PTX in tox studies, and healthy human volunteer studies in NL patients (1.8 gm/d PCS499 vs 1.2 gm/d PTX)
- **PCS499 Treatment Closes All Baseline Ulcers:** In the 2 patients who had ulcers, both patients had complete closing of all their original ulcers
- **PCS499 Treatment Closes New Contact Ulcers:** Closing of contact ulcers also completely healed on PCS499



Open Ulcers at Baseline



Complete Closure at 5 months on 499

Positive PCS499 Phase 2B Placebo Controlled Increases Probability of FDA Approval by Providing Data to Help Design Phase 3 Trial

PCS499

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓

History

- ✓ Chemistry, Manufacturing, Control (CMC), Pcol, Most Tox
- ✓ Phase 1 Human Volunteer Studies (SD, MD, Food Effect)
- ✓ Phase 2A, 2B Trials in DN
- ✓ Phase 2A Demonstrated Safety, Potential Efficacy in uNL

Phase 2B Trial

- ✓ Phase 2B Randomized Placebo Controlled Trial in uNL Patients to Confirm Placebo and 499 Response Rate for Single Phase 3 Trial
- ✓ Obtained Orphan Designation for PCS499 in NL (7-yr Exclusivity)
- ❑ **Increase Exclusivity with Possible New Patents**

Timeline

- ❑ **Phase 2B Initiate Sites, Begin Patient Dosing 4Q'20-1H'21**
- ❑ **Phase 2B Interim Results 4Q'21**
- ❑ **Phase 2B Final Report 4Q'22**
- ❑ **Adaptive Design Phase 3 Pivotal Trial 1H'23**

5HT4 Receptor Agonist, PCS12852, More Potent and Selective to 5HT4 than Other 5HT4 Drugs & Lower Cardiovascular Toxicity Risk

12852 Binds Better to 5HT4 Receptors Than Other Drugs Approved or Being Developed

Compound	5-HT_{4A} receptor		Other 5-HT receptor									
	Binding affinity (IC_{50}, nM)	Agonistic activity (EC_{50}, nM)	Selectivity for 5-HT4 vs. the respective 5-HT subtype (-fold)									
			1A	1B	1D	2A	2B	2C	3A	5A	6	7
YH12852	0.05	0.0048	**1,190**	>10,000	7,300	>10,000	**212**	6,500	>10,000	>10,000	6,150	>10,000
prucalopride	4.2	0.016	**231**	>10,000	NT	>10,000	**106**	NT	NT	NT	NT	>10,000
Tegaserod	15.4	0.25	3	8	16	8	0.5	25	400	20	5	16
Velusetrag (TD-5108)[1-2]	20	5	>500	400	>500	>500	>500	>500	3,000	>500	>500	>500
TAK-954 (TD-8954)[2]	0.4	0.5	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500	>2,500

NT = not tested

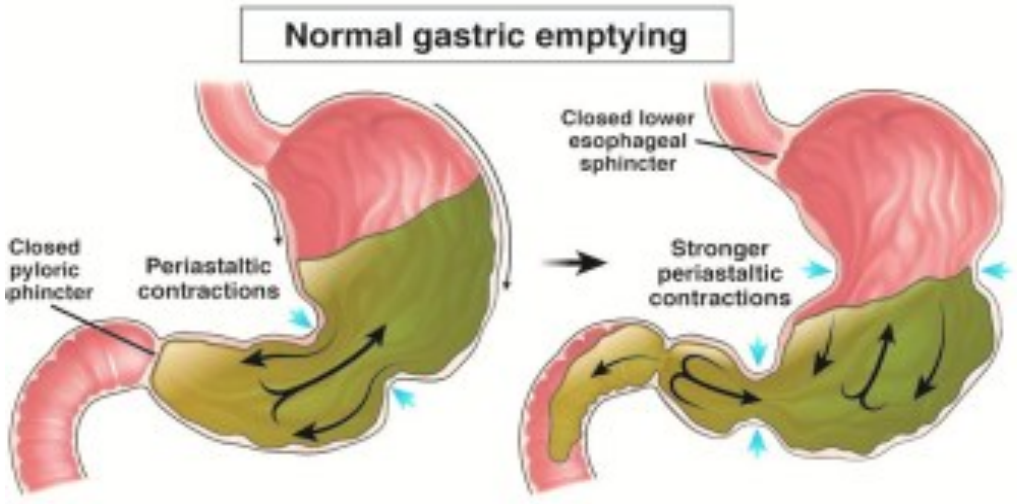
1. *Front Pharmacol. 2011 May 30;2:25*
2. *Gastrointestinal Drugs Advisory Committee Committee-FDA (UCM281534)*

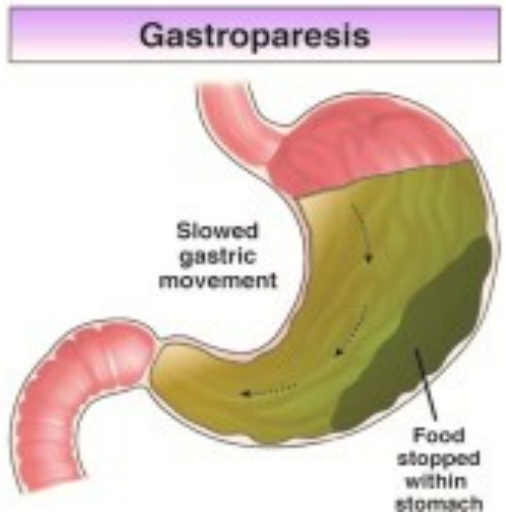
12852 Wider Safety Margin Against Cardiovascular Side Effects than Other 5HT4 Drugs

Measurement	Result	Fold margin at human dose*
hERG inhibition	IC_{50} = 710 nM	**4,300**
Action potential duration in rabbit Purkinje fibers	10% APD90 increase at 220 nM	**1,300**

* Estimated C_{max} multiples based on the free-C_{max} of 3 mg (0.07 ng/mL) in the MAD cohort (healthy males, YH12852-101 study)
APD90 = action potential duration at 90%

PCS12852 Target Population: Present Therapeutic Options for Patients with Gastroparesis Have Serious Side Effects - $1B Market

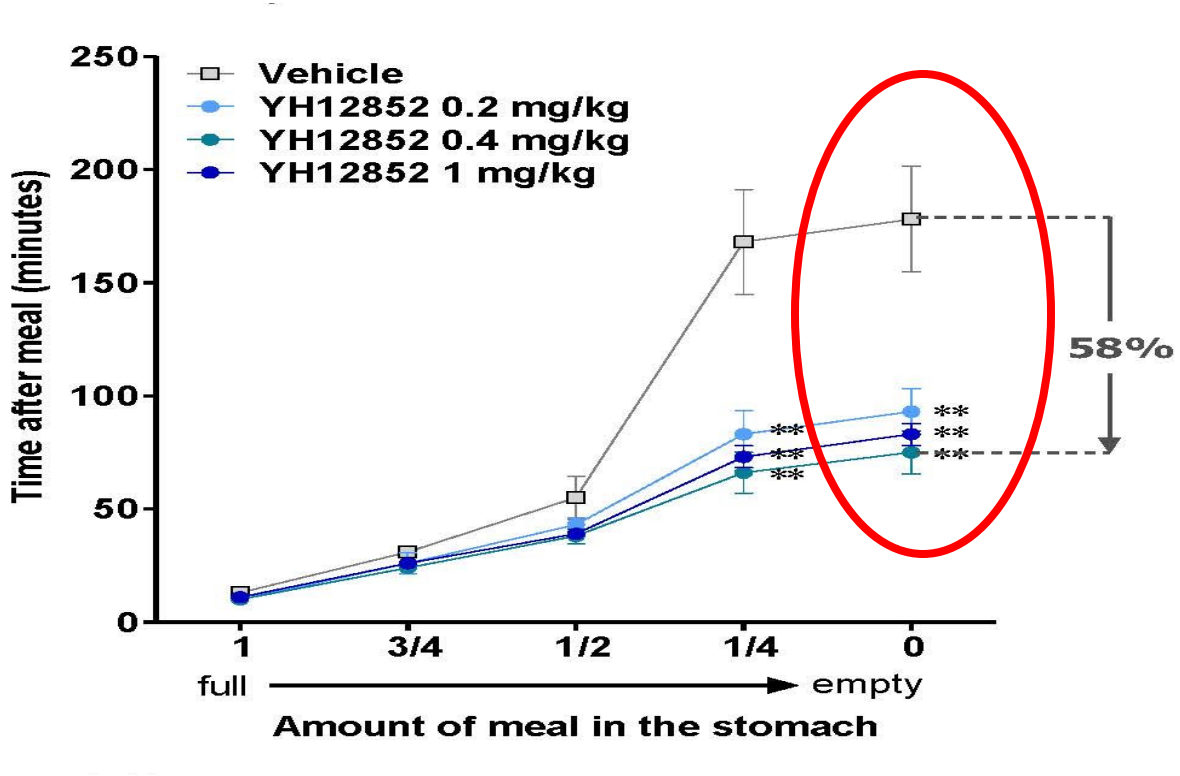




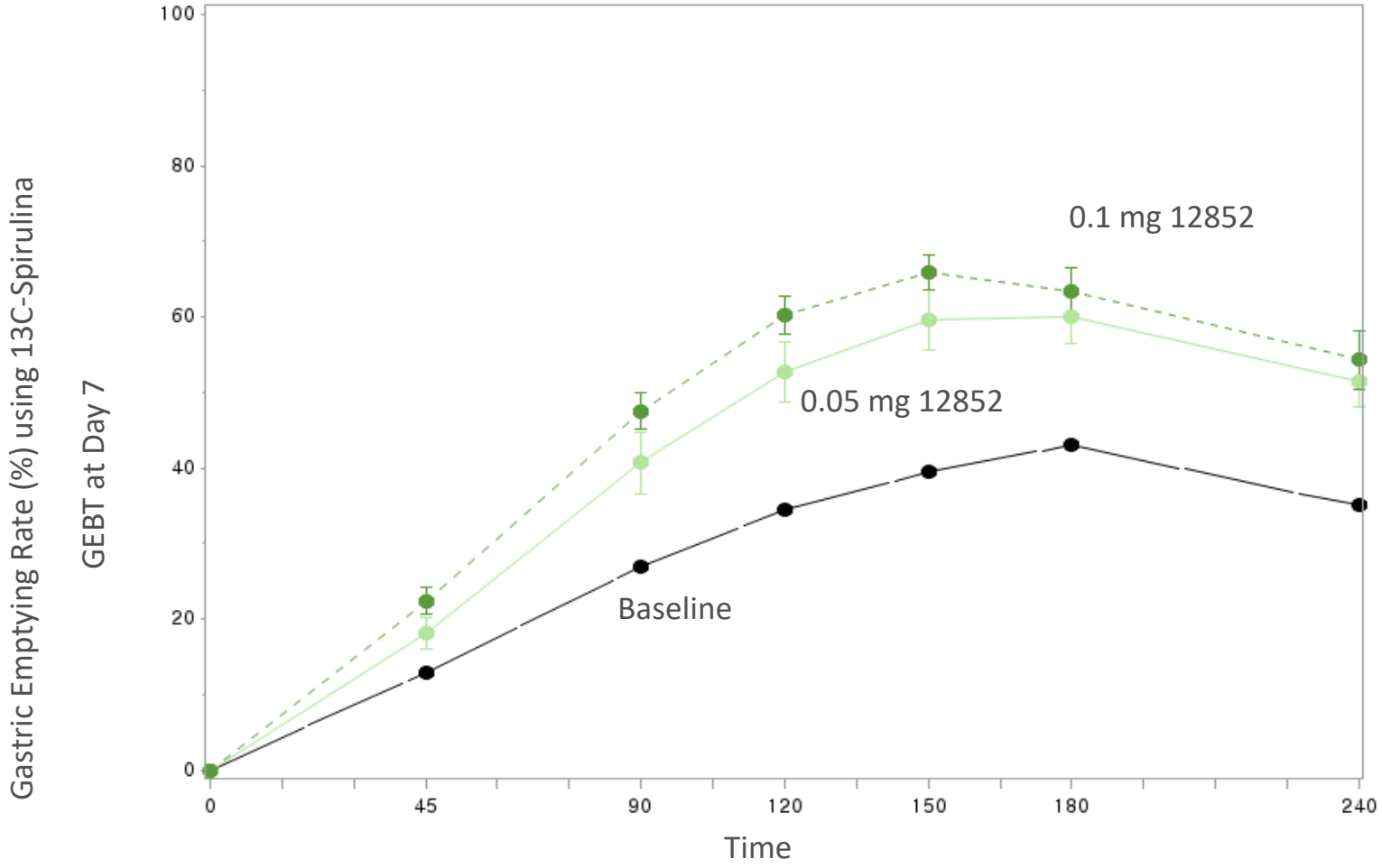
Gastroparesis (prevalence > 4M patients in U.S.) is characterized by delayed gastric emptying in the absence of mechanical obstruction of the stomach. The cardinal symptoms include postprandial fullness (early satiety), nausea, vomiting and bloating. The most common causes of gastroparesis are neuropathic disorders which alter gastric motility.

	12852	Other 5HT4 Drug (eg, Cisapride, Prucalopride, Mosapride)	Dopamine D2 Antagonist (eg, Metoclopramide)
Binding	• Very specific 5HT4 receptor binding • Drug 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 cardiovascular side effects (eg, cisapride removed from market)** • **Suicidal ideation (eg, prucalopride)**	• **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 FDA approved for treatment of gastroparesis

PCS12852: Significantly Accelerates Gastric Emptying Time in Monkeys Better than 5HT4 Agonist Mosapride



PCS12852: Enhanced Gastric Emptying Rate in Patients with Decreased GI Motility Compared to Baseline



Change from baseline in gastric emptying rate increased in 0.1 mg and 0.05 mg PCS12852 groups; Gastric Emptying Breath Test (GEBT) showed a statistically significant change from baseline in the 0.1 mg group.

Positive PCS12852 Phase 2A Trial Increases the Probability of FDA Approval by Providing Data to Help Design Phase 2/3 Trial

History

- ✓ Pharmacology
- ✓ Toxicology,
- ✓ Chemistry, Manufacturing, Control (CMC)
- ❑ New Manufacturing Site Change (Final Product)
- ❑ Pre-IND Meeting, IND Submission

PCS12852

- Unmet Medical Need ✓
- Efficacy Evidence ✓
- Regulatory Science ✓
- Capital Efficiency ✓
- Potentially High ROI ✓

Clinical History

- ✓ Phase 1 Human Volunteer Studies (SD, MD, Food Effect)
- ✓ Proof-of-Concept Demonstrating Efficacy/Safety
- ✓ Patent Exclusivity

Phase 2A to NDA

- ❑ **Finalize Phase 2A Trial Design with KOLs**
- ❑ **FDA IND Submission, Begin Site Initiation 1H'21**
- ❑ **Phase 2A Begin Patient Dosing 2H'21**
- ❑ **Phase 2A Interim Results 1H'22, Completed 2H'22**
- ❑ **Phase 2B/3 To Initiate in 2023**

Summary: How Do We Increase the Value of Processa?

Increase Probability of FDA Approval with Key Interim Results in 2021 & Completion of our 3 Clinical Trials, Providing Data to Design our Larger FDA Registration Trials

	4Q 2020	1Q 2021	2Q 2021	3Q 2021	4Q 2021	1H 2022	2H 2022	2023-2026
PCS6422 Phase 1B	Initiate Sites, ***Begin Patient Dosing***			Trial Ongoing, ***Interim Cohort Results 3Q'21-1H'22***, Final Report 2H'22				Phase 2/3 Trial Initiated 1H'23
PCS499 Phase 2B	Initiate Sites, ***Begin Patient Dosing***			Trial Ongoing, ***Interim Results 4Q'21***, Final Report 4Q'22				Phase 3 Trial Initiated 1H'23
PCS12852 Phase 2A		Pre-IND Meeting, IND, Initiate Sites, ***Begin Patient Dosing 2H'21***			***Interim Results 1H'22***, Trial Completed 2H'22, Final Report 4Q'22			Phase 2B/3 Trial Initiated 1H'23

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, Inc.

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

Khalid Islam, PhD
Director
Chairman of the Board of Fennec Pharmaceuticals