



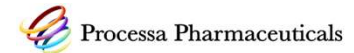
***Next Generation Chemotherapy:
Improved Treatment for
More Patients***

**David Young, Pharm.D., Ph.D.
President and CEO
Processa Pharmaceuticals, Inc
NASDAQ: PCSA**

**MedInvest Oncology Investor Conference
June 21, 2023**



Forward Looking Statement and Disclosures



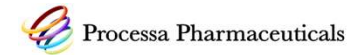
This presentation includes forward-looking statements based upon our current expectations. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions, anticipated milestones, and any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of various risks and uncertainties, which include, without limitation: (i) our ability to raise additional money to fund our operations for at least the next 12 months as a going concern and need to raise additional capital to advance our product candidates and preclinical programs, including in light of current stock market conditions; risks related to our ability to successfully implement our strategic plans, including reliance on our lead product candidate; (ii) uncertainties associated with the clinical development and regulatory approval of product candidates, including in light of our recent and ongoing FDA communications; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (v) intellectual property risks; (vi) the impact of COVID-19 on our operations, enrollment in and timing of clinical trials; reliance on collaborators; reliance on research and development partners; and (vii) risks related to cybersecurity and data privacy.

These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as amended or supplemented by our Quarterly Reports on Form 10-Q and in other filings that we have made and future filings we will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. We expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

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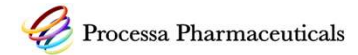
Present Chemotherapy vs. Expectations of Next Generation Chemotherapy



	Present Chemotherapy (Approx %)
Patients Presenting with Cancer Initially Treated with Chemo	20% - 80% of Cancer Patient
<i>Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation</i>	<i>35% - 70% of Patients Treated</i>
Patients Receiving Full Course Prescribed Chemo	30% - 65% of Patients Treated
<i>Patients Responding to Chemo</i>	<i>20% - 40% of Patients Treated</i>
Patients Not Responding to Chemo	60% - 80% of Patients Treated

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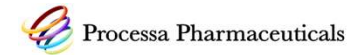
Present Chemotherapy vs. Expectations of Next Generation Chemotherapy



	Present Chemotherapy (Approx %)	Next Generation Chemotherapy (Expected %)
Patients Presenting with Cancer Initially Treated with Chemo	20% - 80% of Cancer Patient	Greater Than Present Chemo
<i>Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation</i>	<i>35% - 70% of Patients Treated</i>	<i>Less Than Present Chemo</i>
Patients Receiving Full Course Prescribed Chemo	30% - 65% of Patients Treated	Greater Than Present Chemo
<i>Patients Responding to Chemo</i>	<i>20% - 40% of Patients Treated</i>	<i>Greater Than Present Chemo</i>
Patients Not Responding to Chemo	60% - 80% of Patients Treated	Less Than Present Chemo

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Next Generation Chemotherapy Overview



Processa Solution

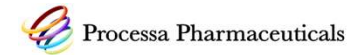
- Develop Next Generation Chemotherapy (NGC) Drugs – Improving Cancer Exposure to ***Widely Used FDA Approved*** Cancer Killing Molecules with a ***Proven History of Therapeutic Success***
- Use Processa Regulatory Science Approach & FDA's Project Optimus Oncology Initiative to ***Define the Optimal Dosage Regimen (ODR)*** for Each NGC as Required by FDA
- NGCs create new opportunities to ***improve treatment and/or impact the side effect profile***



Desired Outcome

- Safer & More Effective Treatment
- ***Improved Likelihood of FDA-Approval in a Short Time***
- ***Significant Investment Upside with Low Risk***
- ***Differentiation from Existing Chemotherapy*** with the Same Active Molecules

Investor Highlights



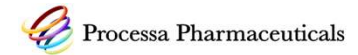
- Clinical stage drug development company with 3 Next Generation Chemotherapy (NGC) drugs with a greater likelihood of FDA approval in ***a more efficient development program***
- ***Multiple NGC milestones*** achievable in 2023 and 2024
- ***Greater than \$1.0B U.S.*** market potential for each NGC used across multiple types of cancer
- ***Potential to out-license or partner*** additional non-NGC drug candidates PCS12852 and PCS499
- Pro-forma ***cash of \$10.7M at 1Q23 provides an operating runway into 2H24***

Processa Pharmaceuticals (NASDAQ: PCSA)	
Stock Price (as of 6/12/23)	\$0.73
Shares Outstanding (as of 5/9/23)	24.5M
Market Capitalization	\$18M
FD Shares Outstanding	~32M
Cash & Equivalents (pro-forma at 3/31/23)	\$10.7M
Insider Ownership	23%

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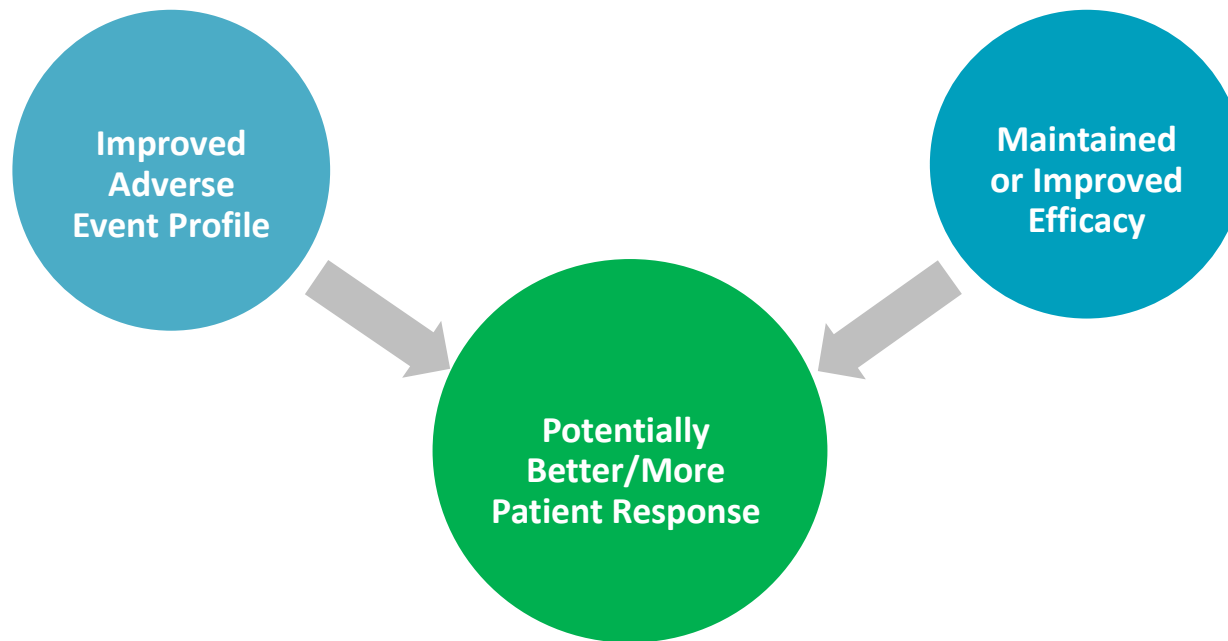
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Processa's NGCs Enhance Potential to Kill Cancer Cells



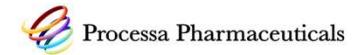
Unique Next Generation Oncology Drugs

Alter Metabolism and/or Distribution of FDA-Approved Cancer Drugs or Their Active Metabolites While Maintaining Existing Mechanism of Killing Cancer



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Optimizing Cancer Treatment

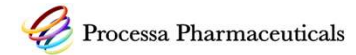


Processa Develops NGCs Using its Regulatory Science Approach and FDA's Project Optimus Oncology Initiative

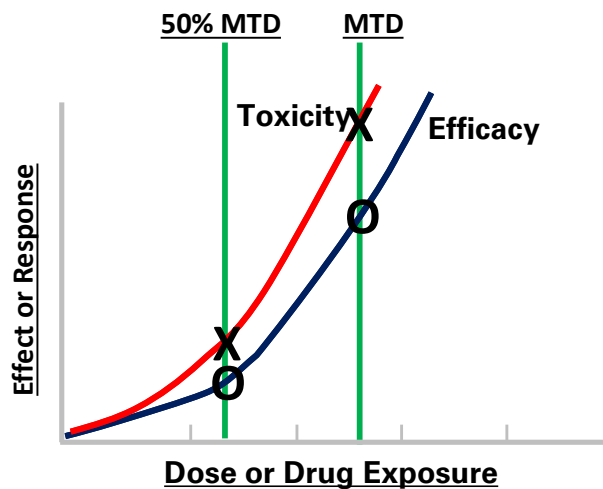
- ***Optimal Dosage Regimen (ODR) creates a better balance between side effects and patient response*** with potentially
 - Fewer side effects
 - Greater effect on the cancer
 - More efficient development/approval process
- ODR approach is required by Project Optimus Initiative
- Processa Founders have developed their Regulatory Science Approach to drug development based on an extensive history of successful drug development with **>30 FDA approvals** for multiple indications since the early 1990s



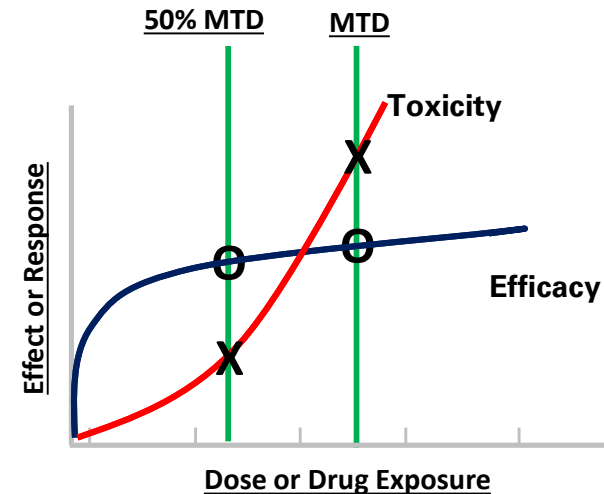
Regulatory Science Approach Utilizes Evaluation of the Exposure-Response Relationship Between Drug and Patient



- **Maximum Tolerated Dose (MTD)** approach assumes the Optimal Dosage Regimen (**ODR**) is the **MTD** and the dose- or exposure-response relationships for toxicity and efficacy follow a similar pattern
- **Project Optimus and Processa Regulatory Science** approach determines the dose- or exposure-response relationships for toxicity and efficacy in order to determine the **ODR**

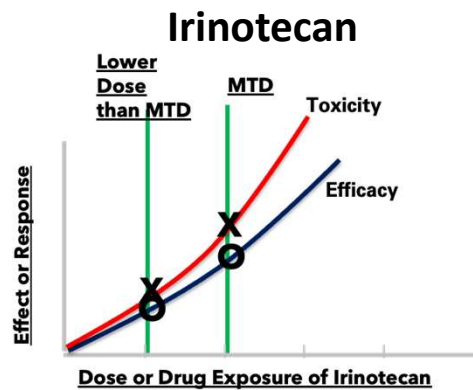
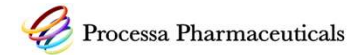


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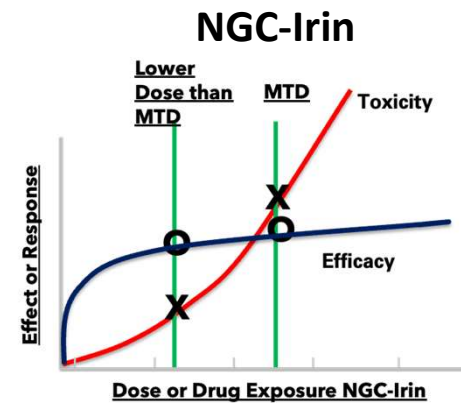


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Case Study: NGC-Irin Dose-Response for Safety and Efficacy Differs from Irinotecan in Animal Cancer Models



Decreasing the dose of Irinotecan below MTD decreases the severity and/or number of adverse events AND ALSO decreases Irinotecan's ability to inhibit cancer

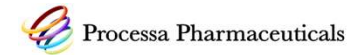


Decreasing the dose of NGC-Irin below MTD decreases the severity and/or number of adverse events but **does NOT significantly change NGC-Irin's ability to inhibit cancer**

Dose	Tumor Growth Inhibition (Efficacy)	
	Irinotecan	NGC-Irin
MTD	85%	100%
½ MTD	64%	100%
¼ MTD	53%	100%

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Processa's Pipeline of Drugs

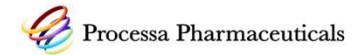


Next Generation Chemotherapies Improving Safety and Efficacy						
Drug	Cancer Indications	Development Stage				
		Preclin	Phase 1	Phase 2	Phase 1	IND
Next Generation Capecitabine (PCS6422)	Hepatocellular, Pancreatic, Colorectal, Breast, Gastric, & Other Solid Tumor Cancers	→		Complete Phase 1B		
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers	→		Proj Opt Phase 2 Re-Analysis		
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers	→	Proj Opt Pre-Clin Re-Analysis			
Candidates for Out-Licensing, Partnering, or Other Monetizing Event						
PCS12852	Moderate/Severe Gastroparesis & Other GI Motility Conditions	→				
PCS499	Ulcerative Necrobiosis Lipoidica (uNL), Side Effects Associated with Chemotherapy, Other	→				

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Processa's Pipeline of Drugs



Next Generation Chemotherapies Improving Safety and Efficacy

Drug	Cancer Indications	Milestones (Anticipated Timeline)
Next Generation Capecitabine (PCS6422)	Colorectal, Hepatocellular, Pancreatic, Breast, Gastric, & Other Solid Tumor Cancers	<input checked="" type="checkbox"/> Colorectal and breast cancer Proof of Concept trials with lower dosing of PCS6422 <input checked="" type="checkbox"/> FDA discussion – Project Optimus & Phase 2 design <input type="checkbox"/> Complete Phase 1B trial (2H2023) <input type="checkbox"/> Initiate Phase 2 start-up tasks (2Q2023) <input type="checkbox"/> Phase 2 interim analysis (2H2024) <input type="checkbox"/> Complete enrollment (End of 2024)
Next Generation Gemcitabine (PCS3117)	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers	<input checked="" type="checkbox"/> Proof-of-concept trials treating naïve and refractory pancreatic cancer patients <input type="checkbox"/> Pancreatic cancer Proj. Opt. data re-analysis, evaluate assay procedures for biomarker eval. (Mid-2023) <input type="checkbox"/> Initiate Phase 2 start-up tasks (2H2023) <input type="checkbox"/> Phase 2 interim analysis (2H2024) <input type="checkbox"/> Complete enrollment (End of 2024)
Next Generation Irinotecan (PCS11T)	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers	<input checked="" type="checkbox"/> Cancer animal study determining dose-response relationship <input type="checkbox"/> Re-analysis of animal dose-response results using Proj. Opt. (Mid 2023) <input type="checkbox"/> Initiate CMC and toxicology IND enabling studies (2H2023) <input type="checkbox"/> Complete IND enabling studies (End of 2024)

Candidates for Out-Licensing, Partnering, or Other Monetizing Event

PCS12852	Moderate/Severe Gastroparesis & Other GI Motility Conditions	<input checked="" type="checkbox"/> Complete Phase 2a proof-of-concept trial <input type="checkbox"/> Out-licensing, partnering, or other opportunities for further development
PCS499	Ulcerative Necrobiosis Lipoidica (uNL), Side Effects Associated with Chemotherapy, Other	<input checked="" type="checkbox"/> Complete open-label Proof of Concept Phase 2a trial <input checked="" type="checkbox"/> Discontinue Phase 2B trial (1H2023) <input type="checkbox"/> Out-licensing, partnering, or other opportunities for further development

Key: ☒ Milestone completed ☐ Milestone in progress ☐ Anticipated milestones in 2023-2024

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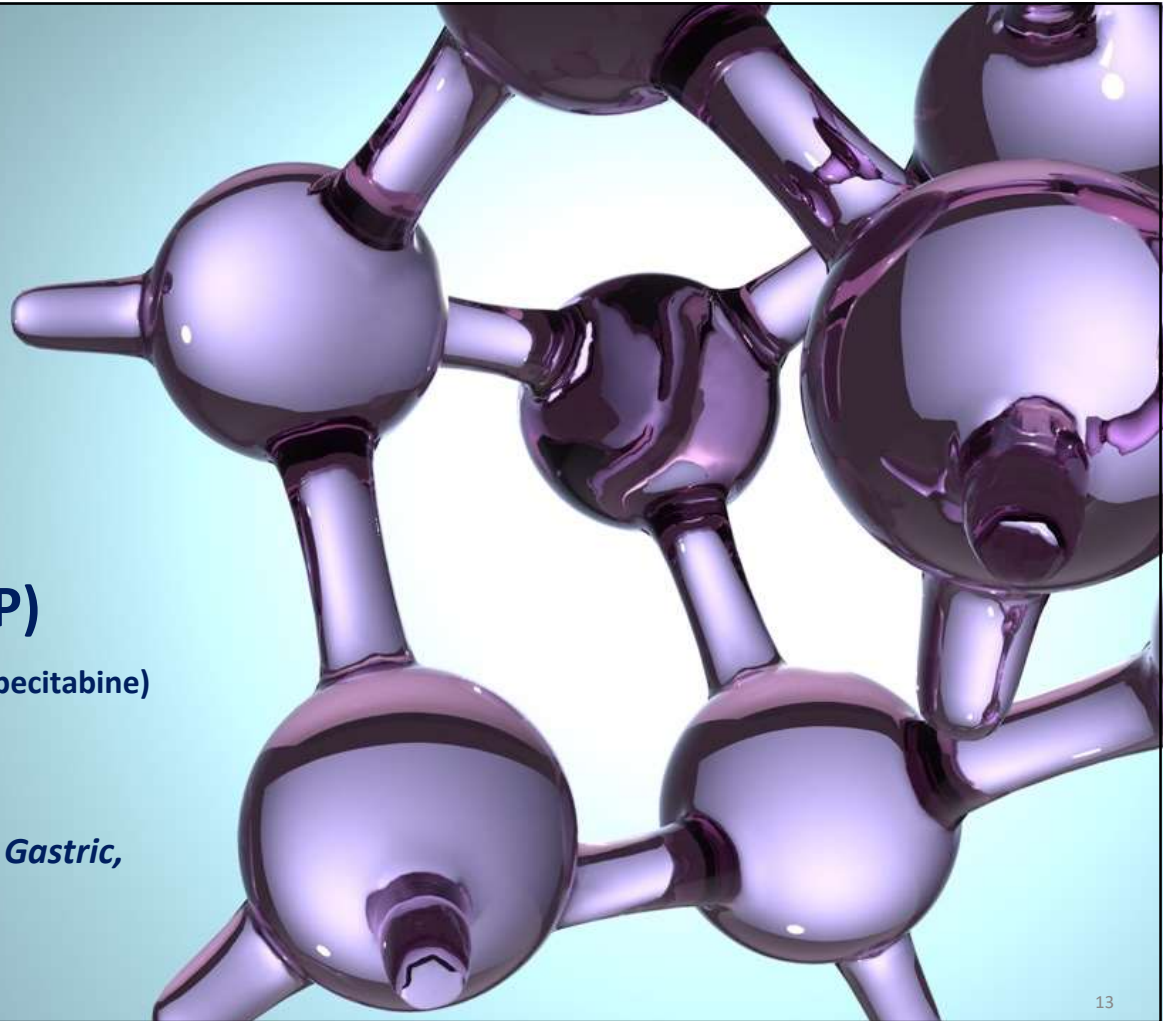


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NEXT GENERATION CHEMOTHERAPY CAPECITABINE (NGC-CAP)

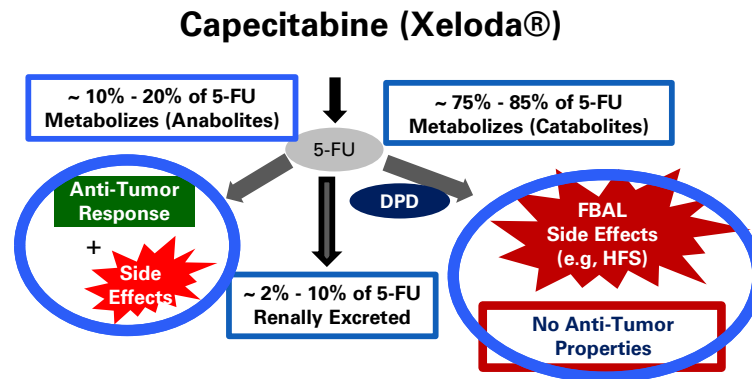
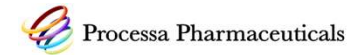
(Combination Regimen of PCS6422 and Capecitabine)

***Colorectal, Pancreatic, Hepatocellular, Gastric,
Breast, and Other Cancers***

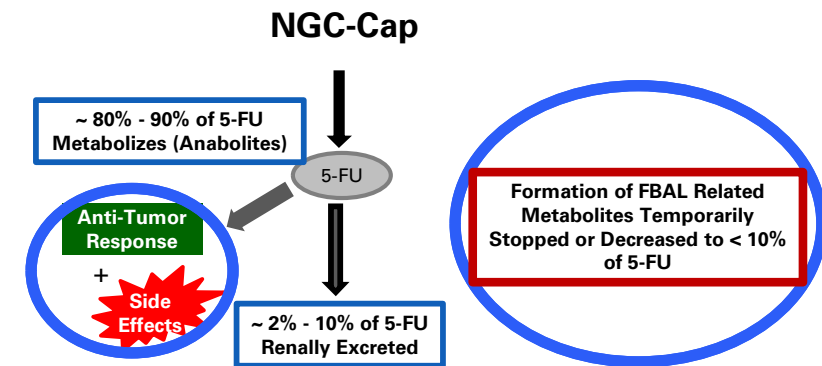


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Capecitabine (Oral Pro-Drug of 5-FU) and 5-FU Are Most Widely Used Cancer Chemotherapy Agents

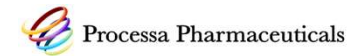


- Therapeutic dose determined by side effects from Catabolites (non-cancer killing molecules) and Anabolites (cancer killing molecules)
- **50% - 70% of patients have dose-limiting side effects from Catabolites** (non-cancer killing molecules) requiring a change in therapy
- **Only 20%-40% of patients respond to Cap**



- **Metabolism of 5-FU to Catabolites no longer occurs, eliminating those side effects**
- Optimal Dosage Regimen to be determined by Project Optimus from only the side effects + anti-tumor response from Anabolites

Highlights of NGC-Cap



	NGC-Cap
Development Commercial	<ul style="list-style-type: none"> • More likely to be FDA approved • More efficient development program than new type of oncology drugs • Develop using Project Optimus & Processa's Regulatory Science Approach • > 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap • U.S. market potential in Cap treated cancer > \$1.0B
Efficacy	<ul style="list-style-type: none"> • Active molecule same as Cap but NGC-Cap may provide improved treatment over Cap • Cancer cells exposed to more 5-FU & Anabolites after NGC-Cap even though dose approx. 5-10% of the typical Cap dose
Side Effects	<ul style="list-style-type: none"> • No side effects from Catabolites in existing Phase 1b trial • Side effects only related to Anabolites observed in Phase 1b trial even though dose is 5-10% of the typical Cap dose (cancer cells exposed to active molecules even with lower dose)
Safety-Efficacy Profile	<ul style="list-style-type: none"> • Based on communications with FDA, Processa has initiated pre-study start-up tasks for the Project Optimus Phase 2 safety-efficacy optimal dosage regimen trial

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Next Milestones of NGC-Cap in 2023

Milestone	Approx. Date
Begin Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing)	2Q2023
Complete Enrollment of Phase 1b MTD Trial	2H2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites	4Q2023
Evaluate Other Regulatory Paths to Approval (e.g., Fast Track)	2023
Prepare Additional Provisional Patent(s)	2023

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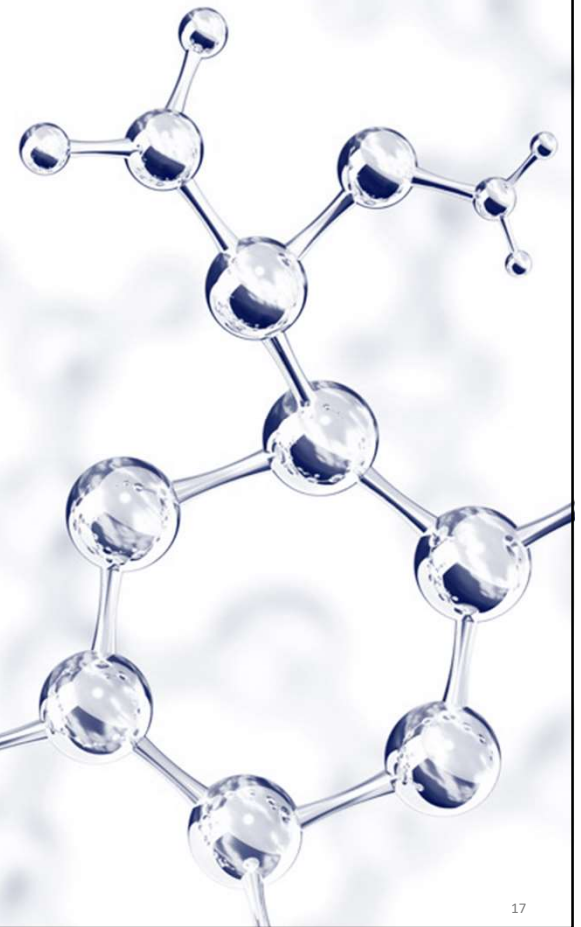




NEXT GENERATION CHEMOTHERAPY GEMCITABINE (NGC-GEM)

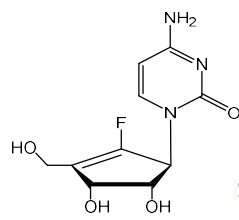
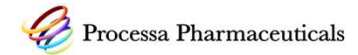
(Chemical Modification of Gemcitabine)

***Pancreatic, Biliary, Ovarian, Non-Small Cell
Lung, and Other Cancers***

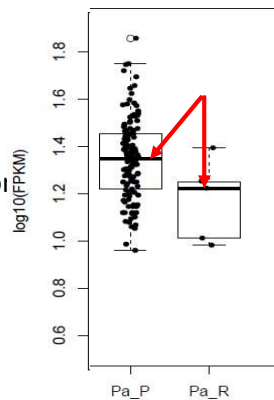


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Next Generation Chemotherapy Gemcitabine (NGC-Gem or PCS3117) and Gemcitabine



RX-3117
Oral
Administration



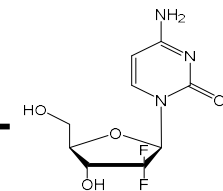
UCK2

Active Cancer
Killing Molecules

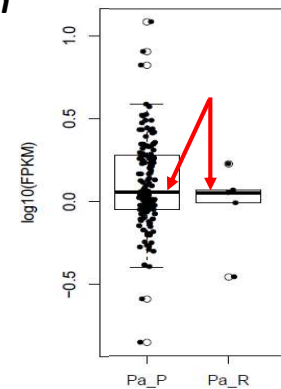
Active Cancer
Killing Molecules

In Some Cancers
UCK2 Expression >> dCK Expression

dCK



Gemcitabine (dFdC)
IV Administration

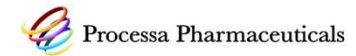


*55% - 85% of Patients Inherently Resistant to
Gemcitabine or Acquire Resistance*

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Highlights of NGC-Gem



	NGC-Gem
Development Commercial	<ul style="list-style-type: none"> • Oral administration rather the intravenous as with Gem • More likely to be FDA approved • More efficient development program than new type of oncology drugs • Developed using Project Optimus & Processa's Regulatory Science Approach • > 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap • U.S. market potential in Cap treated cancer > \$1.0B
Efficacy	<ul style="list-style-type: none"> • Active molecule similar to Gem but there is usually more NGC-Gem activating enzymes (UCK2) than Gem activating enzymes (dCK) potentially resulting in NGC-Gem being more effective than Gem • Cancer cells exposed to more NGC-Gem cancer-killing molecules given more activating enzyme • Working on analytical development of a biomarker assay to identify patients who would respond more to NGC-Gem
Side Effects	<ul style="list-style-type: none"> • Side effect profile similar to Gem
Safety-Efficacy Profile	<ul style="list-style-type: none"> • Phase 2 completed trials resulted in safety-response profile similar to Gem in pancreatic cancer patients as well as patient response in Gem resistant patients • Identify which cancer patients are resistant to Gem and most likely to respond to NGC-Gem to be differentiated from Gem

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Next Milestones of NGC-Gem in 2023



Milestone	Approx. Date
Evaluate Assay Procedure to Measure Potential Biomarkers (Ongoing)	Mid-2023
Re-analyze Clinical Cancer Data Using Project Optimus Approach (Ongoing)	Mid-2023
Meet with FDA to Discuss Phase 2 Trial	2H2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites	2H2023

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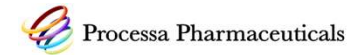
NEXT GENERATION CHEMOTHERAPY IRINOTECAN (NGC-IRIN)

(Chemical Modification of Active Molecule in Irinotecan)

Lung, Pancreatic, Cervical and Other Cancers



Next Generation Chemotherapy-Irinotecan (NGC-Irin): Pro-Drug of SN-38 (Active Metabolite of Irinotecan)



- Cancer killing metabolite of Irinotecan is SN-38
- Irinotecan sales prior to generics > \$1B
- In NGC-Irin, SN-38 linked to Nano-Motor Transporting molecule **allowing for more SN-38 to accumulate in the membranes of cancer cells** than in normal cells
- Extends half-life of SN-38



Irinotecan

Tissue	Exposure	Tumor/ Organ ratio
Tumor	1,153	1
Plasma	172	6.70
Muscle	78	15

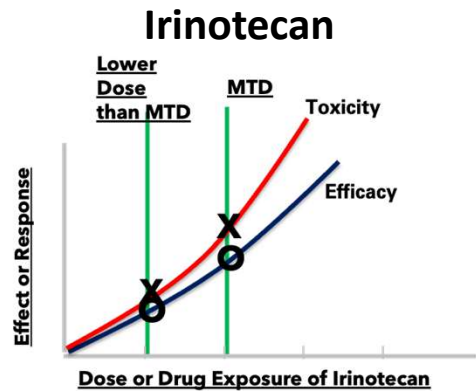
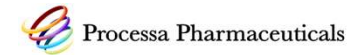
NGC-Irin

Tissue	Exposure	Tumor/ organ ratio
Tumor	3,855	1
Plasma	403	9.57
Muscle	19.2	200

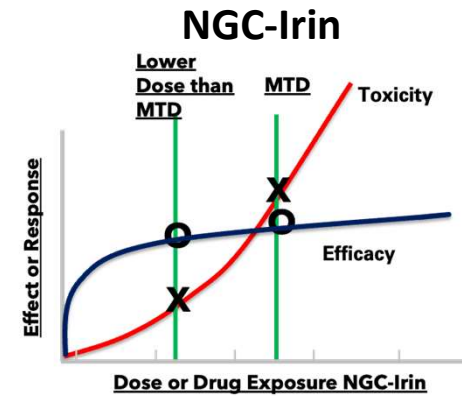
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Case Study: NGC-Irin Dose-Response for Safety and Efficacy Differs from Irinotecan in Animal Cancer Models



Decreasing the dose of Irinotecan below MTD decreases the severity and/or number of adverse events AND ALSO decreases Irinotecan's ability to inhibit cancer



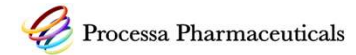
Decreasing the dose of NGC-Irin below MTD decreases the severity and/or number of adverse events but does ***NOT significantly change NGC-Irin's ability to inhibit cancer***

Dose	Tumor Growth Inhibition (Efficacy)	
	Irinotecan	NGC-Irin
MTD	85%	100%
½ MTD	64%	100%
¼ MTD	53%	100%

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Highlights of NGC-Irin



	NGC-Irin
Development Commercial	<ul style="list-style-type: none"> • More likely to be FDA approved • More efficient development program than new type of oncology drugs • Developed using Project Optimus & Processa's Regulatory Science Approach • > 200,000 newly diagnosed patients per year in U.S. with cancers treated with Cap • U.S. market potential in Cap treated cancer > \$1.0B
Efficacy	<ul style="list-style-type: none"> • Active molecule of NGC-Irin (i.e., SN-38) is same active molecule in Irinotecan • Cancer cells exposed to more SN-38 in NGC-Irin because of the MNM-SN38 membrane transporter in NGC-Irin
Side Effects	<ul style="list-style-type: none"> • Given MNM-SN38 specificity for cancer cells over normal cells, it is unlikely that NGC-Irin will have diarrhea and myelosuppression BlackBox
Safety-Efficacy Profile	<ul style="list-style-type: none"> • Pre-clinical animal model results suggest that the MTD approach to defining the Optimal Dosage Regimen probably is not the correct approach to defining the Optimal Dosage Regimen, further supporting the Project Optimus approach

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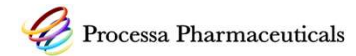
Next Milestones of NGC-Irin in 2023



Milestone	Approx. Date
Select Drug Substance and Drug Product manufacturing site	Mid-2023
Drug development “roadmaps” being developed for lung, pancreatic, colorectal, and other potential cancers	Mid-2023
Complete manufacturing of Drug Substance and Drug Product for toxicology studies	2H2023
Initiate study start-up for IND enabling toxicology studies	2H2023

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Summary of Potential Milestones in 2023



NGC-Cap Milestone	Approx. Date
Begin Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing)	2Q2023
Complete Enrollment of Phase 1b MTD Trial	2H2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites,	4Q2023
Evaluate Other Regulatory Paths to Approval (e.g., Fast Track)	2023
Prepare Additional Provisional Patent(s)	2023

NGC-Gem Milestone	Approx. Date
Evaluate Assay Procedure to Measure Potential Biomarkers (Ongoing)	Mid-2023
Re-analyze Clinical Cancer Data Using Project Optimus Approach (Ongoing)	Mid-2023
Meet with FDA to Discuss Phase 2 Trial	2H2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites	2H2023

NGC-Irin Milestone	Approx. Date
Select Drug Substance and Drug Product manufacturing site	Mid-2023
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Complete manufacturing of Drug Substance and Drug Product for toxicology studies	2H2023
Initiate study start-up for IND enabling toxicology studies	2H2023

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Processa Senior Management



David Young, Pharm.D, Ph.D.
President & CEO

Joined Processa 2018

Former Roles:

- CSO & Independent Director, Questcor
- U.S. President, AGI Therapeutics
- CEO, GloboMax
- Associate Professor, University of Maryland
- Pharm.D., PhD, University of S. California



Sian Bigora, Pharm.D.
Chief Development Officer

Joined Processa 2018

Former Roles:

- VP Regulatory, Questcor
- VP Clinical Research, AGI Therapeutics
- VP Regulatory, ICON Plc, GloboMax
- Clinical Research Assoc., Univ. of Maryland
- Pharm.D., University of Maryland



Michael Floyd
Chief Operating Officer

Joined Processa 2020

Former Roles:

- President & CEO, Elion Oncology
- U.S. Project Lead, Gentium
- President, Arpida
- BSBA, Georgetown University



Patrick Lin
Chief Business & Strategy Officer

Joined Processa 2018

Former Roles:

- Founder and Managing Partner, Primarius Capital
- Robertson Stephens & Co.
- Co-Founding Partner, E*Offering
- MBA, Kellogg Graduate School; BS, University of S. California



James Stanker, CPA
Chief Financial Officer

Joined Processa 2019

Former Roles:

- Audit Partner, Grant Thornton
- CFO, NASDAQ listed company and a privately-held life science company
- Director/Audit Committee Chairman, Hesperos
- MBA, California State University; BS, San Jose University



Wendy Guy
Chief Administrative Officer

Joined Processa 2018

Former Roles:

- Senior Manager, Business Operations, Questcor
- Senior Manager, AGI Therapeutics
- Senior Manager, Administration, ICON Plc, GloboMax
- AA, MWCC

NASDAQ: PCSA

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Investor Summary



- Clinical stage drug development company with a robust pipeline of 3 ***Next Generation Chemotherapy (NGC) drug candidates with the potential to improve the treatment of patients with multiple types of cancers***
- Number of Key Milestones achievable over the ***next 12 months***
- Management with significant drug development experience that is aligned with FDA's Project Optimus Oncology Initiative to define the ***Optimal Dosage Regimens*** for each cancer drug
- Given an improved safety and efficacy profile, more patients should benefit from NGCs and more patients should be treated providing a ***U.S. market potential of >\$1.0B for each NGC***
- Management Team Involved With ***Billion-Dollar Exits*** (Questcor - \$5.7B & Gentium - \$1.0B)
- Potential to out-license or partner non-NGC drug candidates PCS12852 and PCS499
- Pro-forma cash of \$10.7M at 1Q23 provides an ***operating runway into 2H24***

NASDAQ: PCSA

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The background of the slide features a stylized illustration of two hands, constructed from a network of blue lines and dots, holding two glowing blue capsules. A trail of smaller glowing blue spheres falls from the point where the capsules meet. In the top left corner, there is a small, glowing blue capsule. The overall color scheme is dark blue with glowing cyan and blue elements.

 **Processa Pharmaceuticals**

NASDAQ: PCSA

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