



Processa Pharmaceuticals

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

**Corporate Presentation**  
**January 2024**



# 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.

## Next-Generation Chemotherapies (NGCs) Designed to Improve Survival and Quality of Life for Cancer Patients

- A de-risked strategy of developing new chemical entities (NCEs) based on improving pharmacokinetics of existing, proven treatments.
- Management team with decades of experience taking drugs through the FDA's approval process using our proven Regulatory Science Approach which focuses on reforming dose optimization based on maintaining or improving efficacy while reducing toxicities.
- Actively advancing three anti-cancer NCEs, two in clinical development and one near clinic-ready.
- Potential to out-license or partner non-NGC and select NGC drug candidates.

### Processa Pharmaceuticals (NASDAQ: PCSA)

Stock Price (as of 01/04/24)	\$0.35
Shares Outstanding (as of 12/31/23)	24.6M
Market Capitalization	\$8.6M
Cash & Equivalents (at 9/30/23)	\$6.9M
Insider Ownership	23.2%



**George Ng**  
*Chief Executive Officer*

## **Joined Processa 2023**

### **Former Roles:**

- President, COO, & Director, Calidi Biotherapeutics
- Partner, PENG Life Science Ventures
- Founder and President, Scilex Pharmaceuticals
- JD, University of Notre Dame; B.A.S. Dual Degree, University of California, Davis



**Patrick Lin**  
*Chief Business & Strategy Officer*

## **Joined Processa 2017**

### **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



**David Young, Pharm.D, Ph.D.**  
*President, Research and Development*

## **Joined Processa 2017**

### **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



**James Stanker, CPA**  
*Chief Financial Officer*

## **Joined Processa 2018**

### **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



**Sian Bigora, Pharm.D.**  
*Chief Development Officer*

## **Joined Processa 2017**

### **Former Roles:**

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



**Wendy Guy**  
*Chief Administrative Officer*

## **Joined Processa 2017**

### **Former Roles:**

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

- More than 200,000 new cancer diagnoses worldwide across multiple indications for each NGC in development.
- NGC compounds will potentially address efficacy and toxicity at an **optimized** dose to show **improvement over** standard of care.
- Development process aligns with FDA's Oncology Center of Excellence Project Optimus initiative to reform dose optimization and dose selection<sup>1</sup>.
- With these improved, newer chemotherapies, either as new singular agents or combinations, we can potentially deliver better oncology therapies.

<sup>1</sup><https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus>



## Next Generation Chemotherapies Improving Safety and Efficacy

Drug	Cancer Indications	Development Stage				
		Preclin	Phase 1	Phase 2	Phase 3	NDA
<b>Next Generation Capecitabine (PCS6422)</b>	Colorectal, Breast, Hepatocellular, Pancreatic, Gastric, & Other Solid Tumor Cancers	Phase 1b Near Completion				
<b>Next Generation Gemcitabine (PCS3117)</b>	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers	Phase 2a Completed				
<b>Next Generation Irinotecan (PCS11T)</b>	Pancreatic, Ovarian, Lung, Colorectal, Gastric, Cervical & Other Cancers	Pre-clinical				

# How Our Oncology Assets Differ from Current Chemotherapy

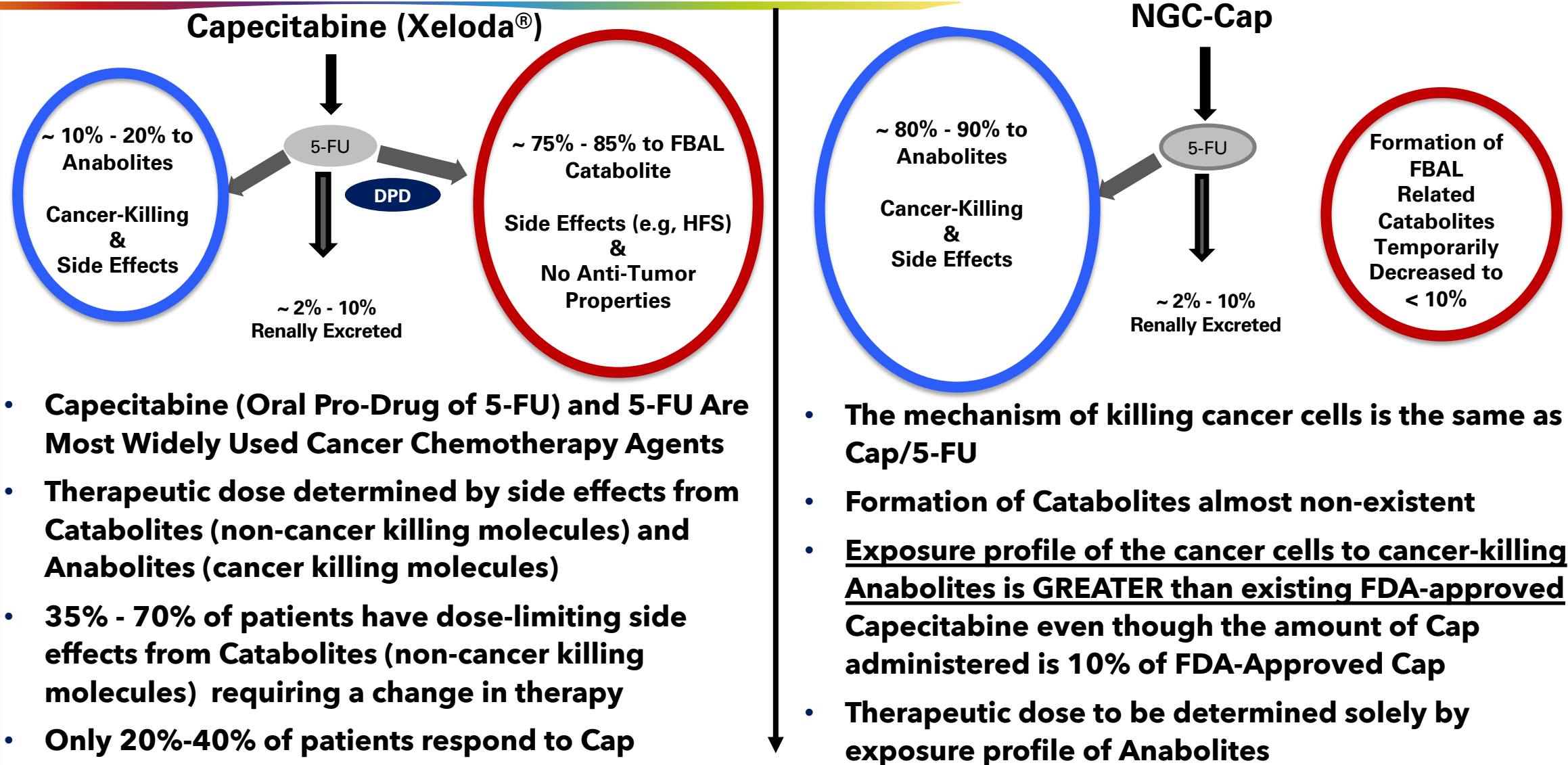
Standard of Care Problem	Potential Patient Benefits with Our NGCs
<b><u>Capecitabine</u></b> - Low treatment response with high side effect profile.	Change in metabolism and distribution of cancer-killing molecules that <b><i>reduces AEs and expands patient pool.</i></b>
<b><u>Gemcitabine</u></b> -High drug resistance and/or acquired resistance; administered as IV.	<b><i>Oral therapy</i></b> that increases metabolism to cancer-killing molecules, <b><i>increasing the amount</i></b> of cancer-killing molecules and <b><i>limiting resistance.</i></b>
<b><u>Irinotecan</u></b> - Significant side-effect profile limits dosing and drug use.	Cancer-killing molecules <b><i>preferentially enter cancer cells over normal cells</i></b> to provide <b><i>additional efficacy</i></b> with <b><i>less toxicity.</i></b>

# PCS6422 / Next Generation Capecitabine (NGC-Cap)

	NGC-Cap
<b>Efficacy</b>	<ul style="list-style-type: none"><li>• Alters metabolism to increase distribution of 5-FU and cancer-killing molecules to cancer cells while reducing the metabolites that only cause side effects</li><li>• Active molecule same as Capecitabine but provides improved treatment at a lower dose</li></ul>
<b>Side Effects</b>	<ul style="list-style-type: none"><li>• Better side effect profile</li></ul>
<b>Clinical Development</b>	<ul style="list-style-type: none"><li>• Ongoing Phase 1B trial with expected enrollment completed YE 2023</li><li>• Based on the FDA meeting in December 2023, anticipate Phase 2 trial to begin enrolling patients in mid-2024</li></ul>



# NGC-Cap Not the Same Treatment or Drug as FDA-Approved Capecitabine

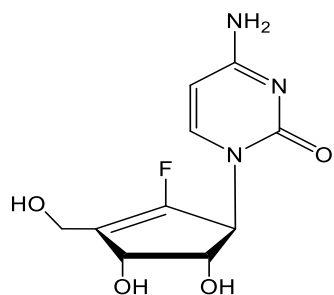


# PCS3117 / Next Generation Gemcitabine (NGC-Gem)

## Oral Drug with Same MOA as Gemcitabine

	NGC-Gem
<b>Efficacy</b>	<ul style="list-style-type: none"><li>Provides improved treatment over Gemcitabine seen in previous pancreatic cancer trial data; cancer cells exposed to more NGC-Gem cancer-killing molecules given more activating enzyme</li></ul>
<b>Side Effects</b>	<ul style="list-style-type: none"><li>Side effect profile similar to Gemcitabine</li></ul>
<b>Clinical Development</b>	<ul style="list-style-type: none"><li>Company to collaborate with FDA on the development program, including target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm within the trial</li></ul>

# NGC-Gem (Oral): Increase Metabolism to Cancer-Killing Molecules Given Different Metabolizing Enzyme than Gemcitabine (IV)



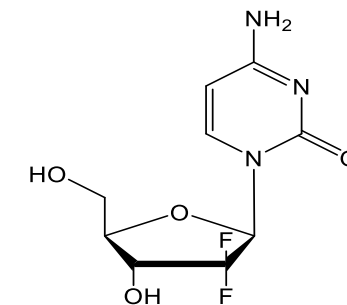
NGC-Gem  
Oral  
Administration

UCK2

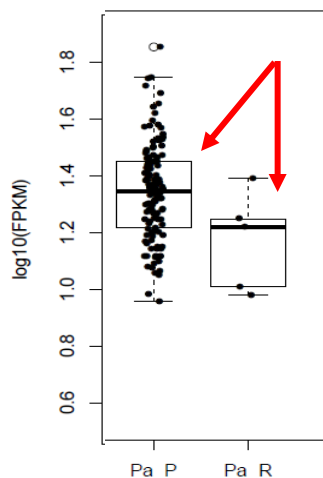
Active Cancer  
Killing  
Molecules

Active Cancer  
Killing  
Molecules

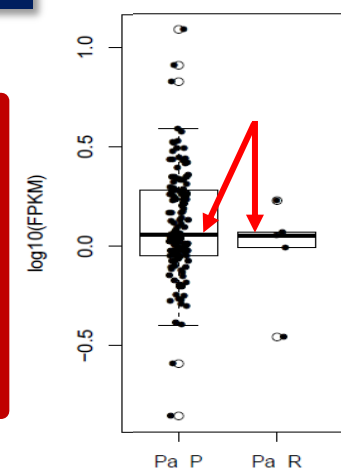
dCK



Gemcitabine  
(dFdC)  
IV Administration



***In Some Cancers  
UCK2 Expression >> dCK Expression  
Resulting in Metabolism to More  
Cancer-Killing Molecules  
for NGC-Gem than Gem***



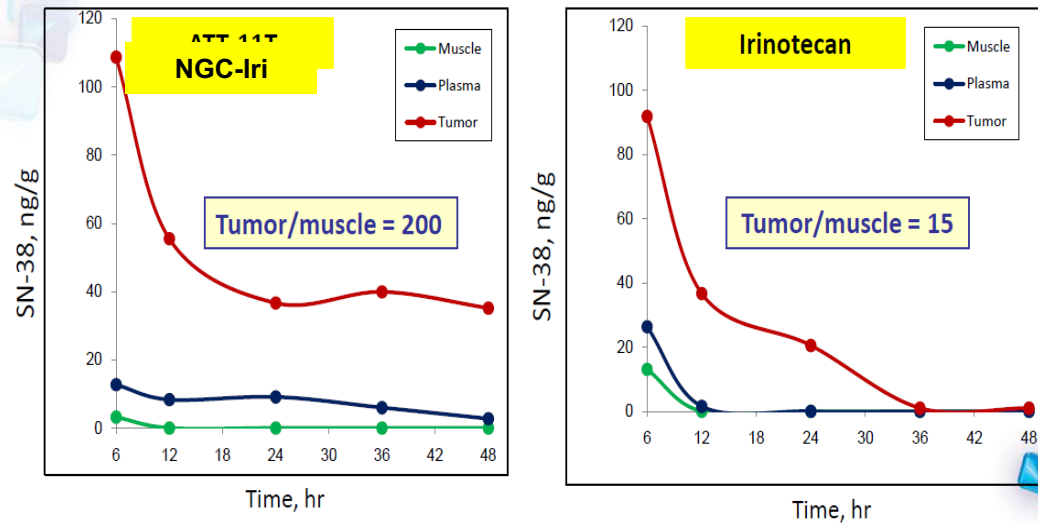
***55% - 85% of Patients Inherently Resistant  
to Gemcitabine or Acquire Resistance***

# PCS11T / Next Generation Irinotecan (NGC-Iri)

	NGC-Iri
<b>Efficacy</b>	<ul style="list-style-type: none"><li>• Active molecule SN-38 is same active molecule in Irinotecan</li><li>• Distributes SN-38 differently, entering the cell membrane of cancer cells preferentially over normal cells, improving cancer-killing effect</li></ul>
<b>Side Effects</b>	<ul style="list-style-type: none"><li>• Given MNM-SN38 specificity for cancer cells over normal cells, animal data suggests fewer side effects; likely that patients will have less diarrhea and less myelosuppression (a BlackBox warning for Irinotecan)</li></ul>
<b>Clinical Development</b>	<ul style="list-style-type: none"><li>• Expand pre-clinical analysis with additional ongoing pre-clinical efficacy study</li><li>• Evaluating sites to manufacture PCS11T</li><li>• Pre-IND enabling toxicology studies and CMC studies to be completed prior to IND submission</li></ul>

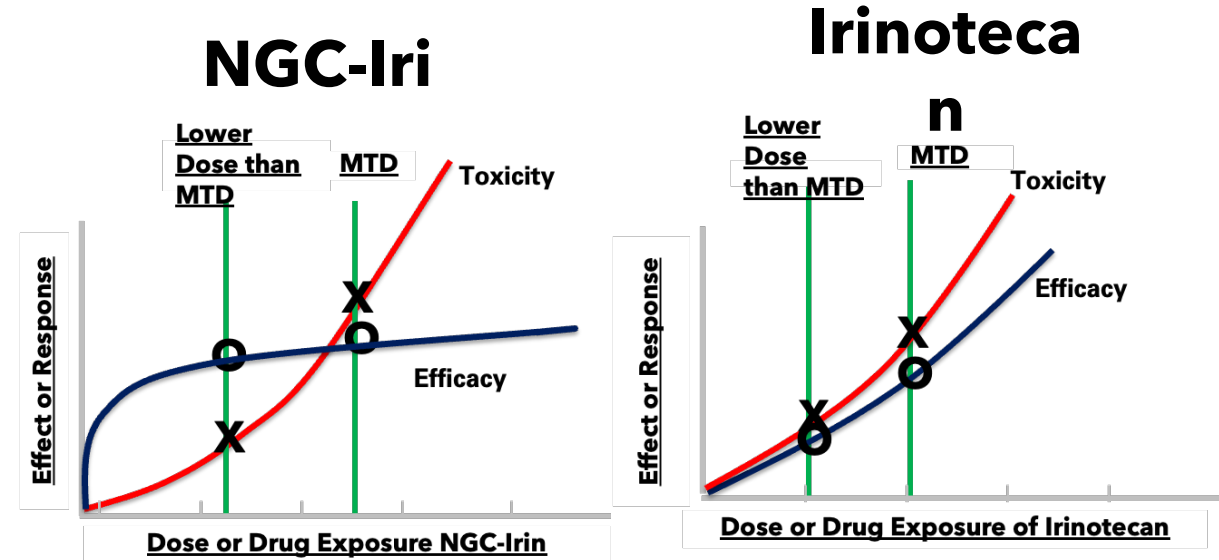
# NGC Irinotecan: Higher Amounts & Lower Required Dose

**Tumor-Bearing Mice Had 200x Higher Drug In Tumor vs Muscle Compared To 15x With Irinotecan**



Tissue	NGC-Iri AUC (ng/g*hr)	NGC-Iri Tumor/Tissue Ratio	Irinotecan AUC (ng/g*hr)	Irinotecan Tumor/Tissue Ratio
Tumor	3,855	1	1,153	1
Plasma	403	9.57	172	6.7
Muscle	19.2	200	78	15

**Efficacy Maintained at Lower Doses of NGC-Iri When Compared to Irinotecan in SW620 Colorectal Cancer Xenograft Model**



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

# Summary of Activities/Milestones

Milestone	Approx. Date
NGC-Cap: Cohort Review Committee Meeting to Determine if Phase 1B MTD Trial Enrollment Completed	January 2024
NGC-Cap: Finish Defining Regulatory Paths to Approval and ODR Phase 2 Design based on FDA Communications	1Q2024
NGC-Cap: Submit Phase 2 Protocol to IND, Begin Initiating Sites	1H2024
NGC-Gem: Define Regulatory Paths to Approval and ODR Phase 2 and 3 Designs with FDA	2Q-3Q2024
NGC-Gem: Submit ODR Phase 2 or 3 Protocol to IND and Begin Study Preparation	2Q-3Q2024
NGC-Iri: Preclinical Tox Study Preparation	1H2024



# Why Processa Now?

- Upcoming Catalysts/Milestones:
  - PCS6422/NGC-Cap
    - Complete Phase 1B enrollment & dose regimen safety evaluation.
    - Finalize Phase 2 study design based on FDA feedback.
    - Initiate Phase 2 study and patient enrollment.
  - PCS3117/NGC-Gem
    - Collaborate with FDA to further define development program (target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm).
- New CEO (joined 2H 2023) with extensive turnaround, BD track record and significant oncology experience.
- Potential non-core asset out-licensing transaction(s) to generate non-dilutive funds

## **Up-Side Opportunity with a Strategy of Optimizing Proven Therapeutics via NCEs**

- Developing Next-Generation Chemotherapy (NGC) drugs with near term achievable milestones using cancer-killing molecules presently in FDA-approved drugs.
- NCEs with potential for expanded use in multiple cancer indications due to favorable profiles.
- Experienced management team with multiple regulatory approvals and successful exits.
- > Billion-dollar US market potential across multiple cancer types.
- Cash of \$6.9M as of September 30, 2023 provides an operating runway into 2H2024.
- Potential to out-license or partner non-NGC and select NGC drug candidates.



# Processa Pharmaceuticals



**NASDAQ: PCSA**

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