



Processa Pharmaceuticals

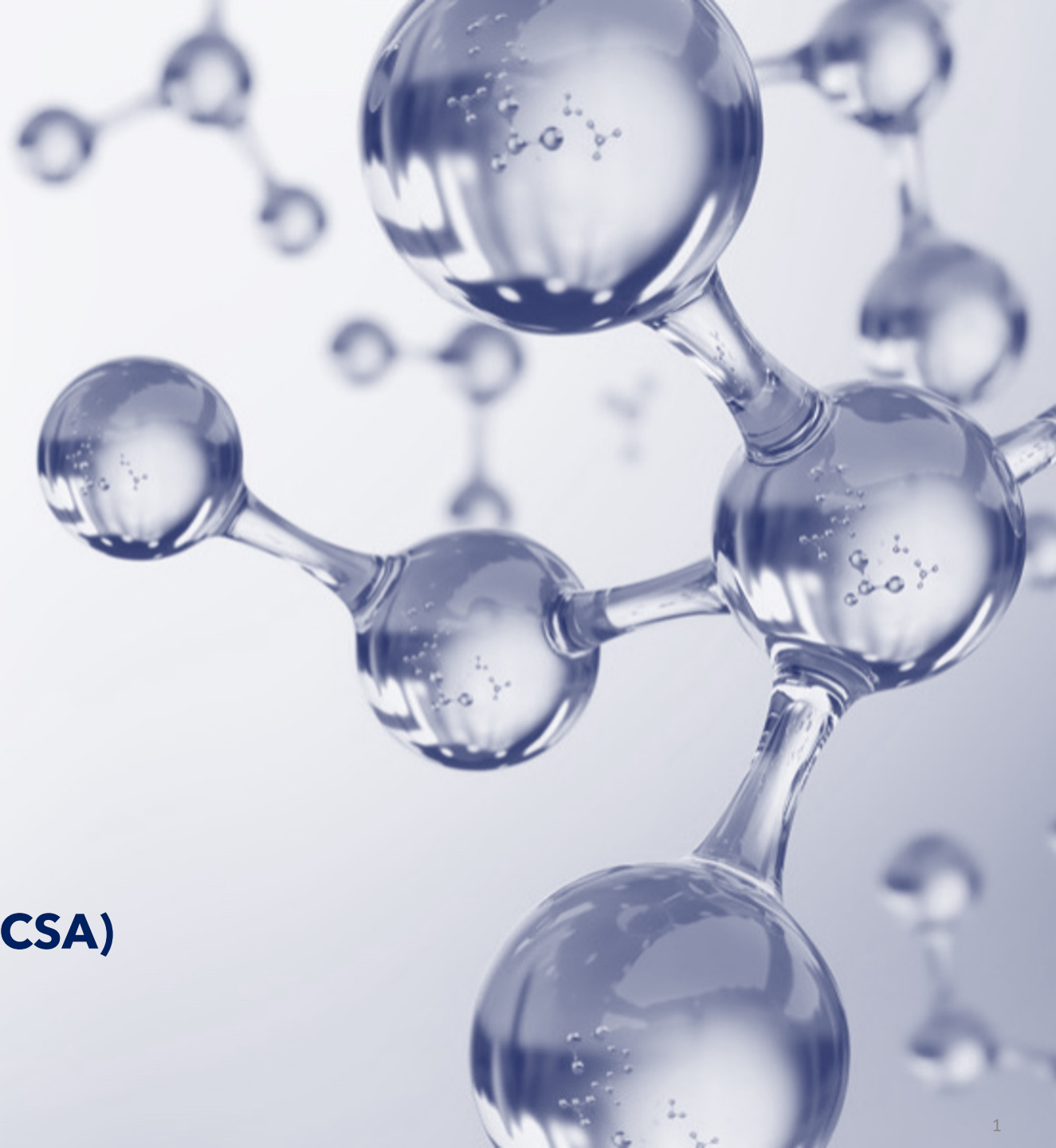
***Next Generation Chemotherapy:
Improved Treatment for
More Patients***

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

**George Ng
Chief Executive Officer**

Processa Pharmaceuticals, Inc (NASDAQ: PCSA)

**MedInvest Oncology Investor Conference
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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.

Developing the Next-Generation Chemotherapies (NGCs) Designed to Improve Survival and Quality of Life for More 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 obtaining > 30 FDA approvals for indications across FDA Divisions** using our proven Regulatory Science Approach and focusing on defining the Optimal Dosage Regimen (ODR) to improve the efficacy-safety profile
- **Actively advancing three anti-cancer NCEs**, two with INDs and one near clinic-ready, that are better versions of three of the most widely used existing chemotherapy drugs
- **Potential to out-license or partner** non-NGC and select NGC drug candidates

Processa Pharmaceuticals (NASDAQ: PCSA)

Stock Price (as of 11/30/23)	\$0.64
Shares Outstanding (as of 11/1/23)	24.6M
Market Capitalization	\$15.8M
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:

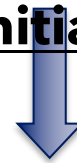
- Senior Manager, Business Operations, Questcor
- Senior Manager, AGI Therapeutics
- Senior Manager, Administration, ICON Plc, GloboMax
- AA, MWCC

Each Next Generation Chemotherapy (NGC): Potential Annual Sales of > \$500M - \$1B

	Present Chemotherapy (Approx % Pts)	NGC (Expected %)
Patients Experiencing Side Effects That Require Dose Reduction or Discontinuation	35% - 70%	
Patients Receiving Full Course Prescribed Chemo	30% - 65%	
Number of Patients Responding to Chemo	20% - 40%	
Patients Initially Treated with Chemo	20% - 80% of Cancer Patient	

How Do NGCs Improve the Safety-Efficacy Profile While Treating More Patients?

- Each NGC **Mechanism of Killing Cancer Cells Remains the Same as Existing FDA-Approved Drug**
- **Alter Metabolism/Distribution** of FDA-Approved Cancer Drug or Active Molecules Results in **More Exposure of Cancer Cells to Cancer-Killing Molecules**
- **Define the Optimal Dosage Regimen (ODR) for NGCs** with Processa's Regulatory Science Approach **Applying FDA's Project Optimus Oncology Initiative**



- **Improve Safety**
- **Improve Efficacy**
- **Treat More Patients**

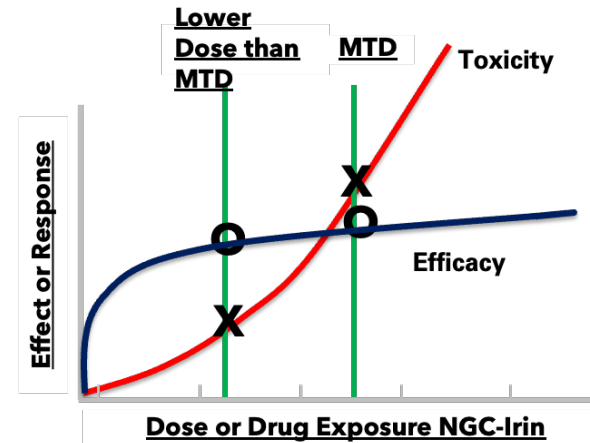
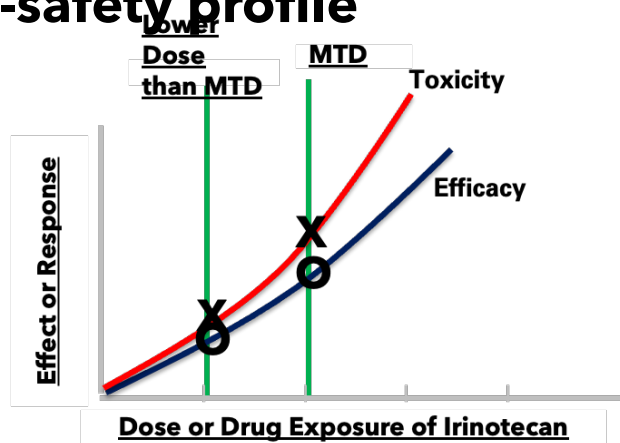
Our NGCs Differ from Current Chemotherapy

Standard of Care Problem	Potential Patient Benefits with Our NGCs
<u>Capecitabine</u> - High side effect profile resulting in dose reduction, treatment discontinuation, and less response	By changing metabolism and distribution of cancer-killing molecules, AEs may be reduced, efficacy improved, and the number of patients treated expanded
<u>Gemcitabine</u> -High drug resistance and/or acquired resistance; administered as IV	Oral therapy that increases metabolism to cancer-killing molecules, increases the exposure to cancer-killing molecules, and decreases resistance
<u>Irinotecan</u> - Significant side-effect profile limits dosing and drug use	Cancer-killing molecules preferentially enter cancer cells over normal cells to provide additional efficacy with less toxicity

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

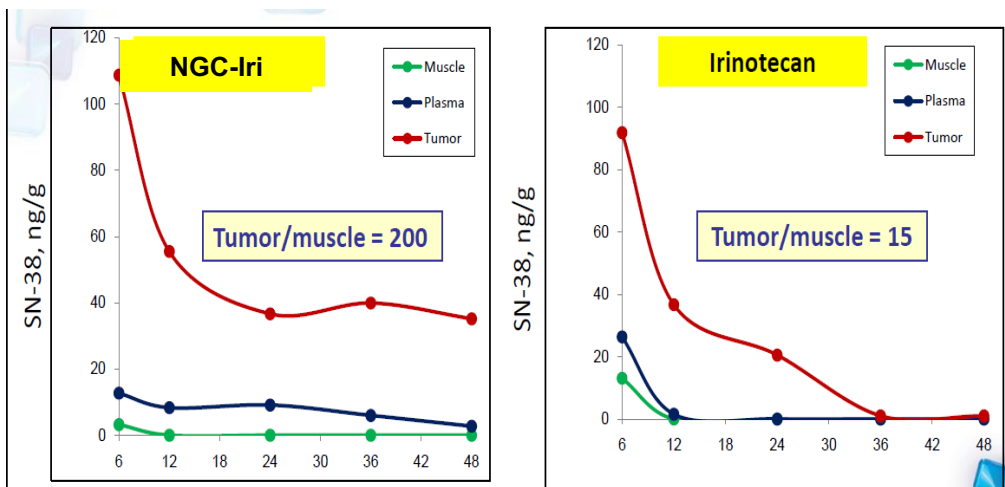
Processa Develops NGCs Using its Regulatory Science Approach and FDA's Project Optimus Oncology Initiative

- **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 FDA Project Optimus Initiative and ODR Draft Guidance
- **Management team with Regulatory Science Approach to define the Optimal Dosage Regimen (ODR) to improve the efficacy-safety profile**



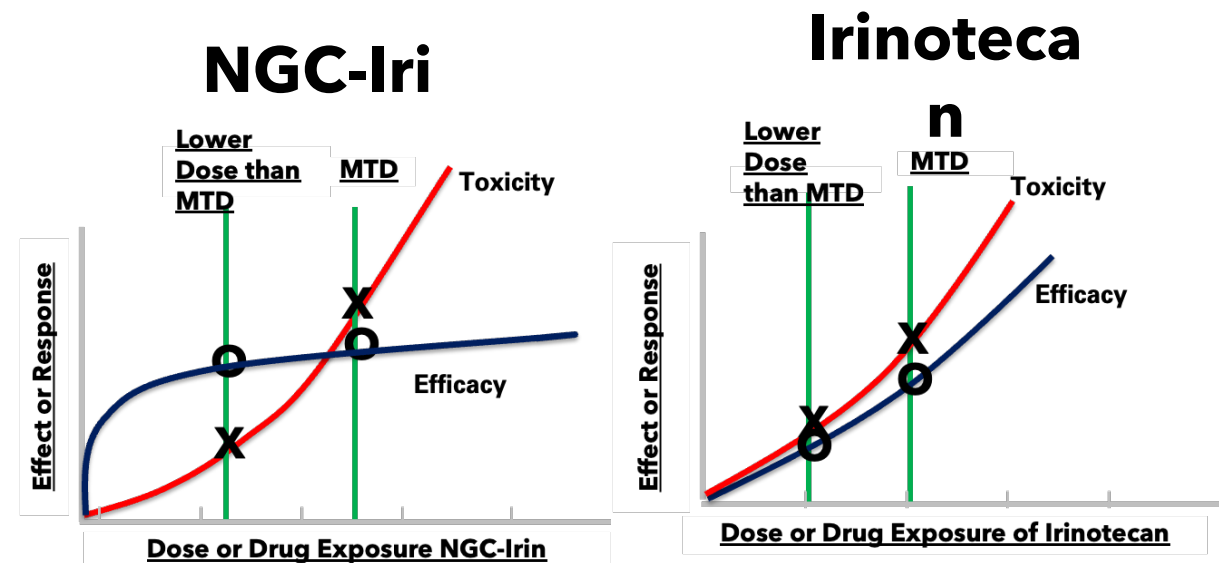
Project Optimus Example: Next Generation Irinotecan

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	NGC-Irin
MTD	100%	85%
½ MTD	100%	64%
¼ MTD	100%	53%

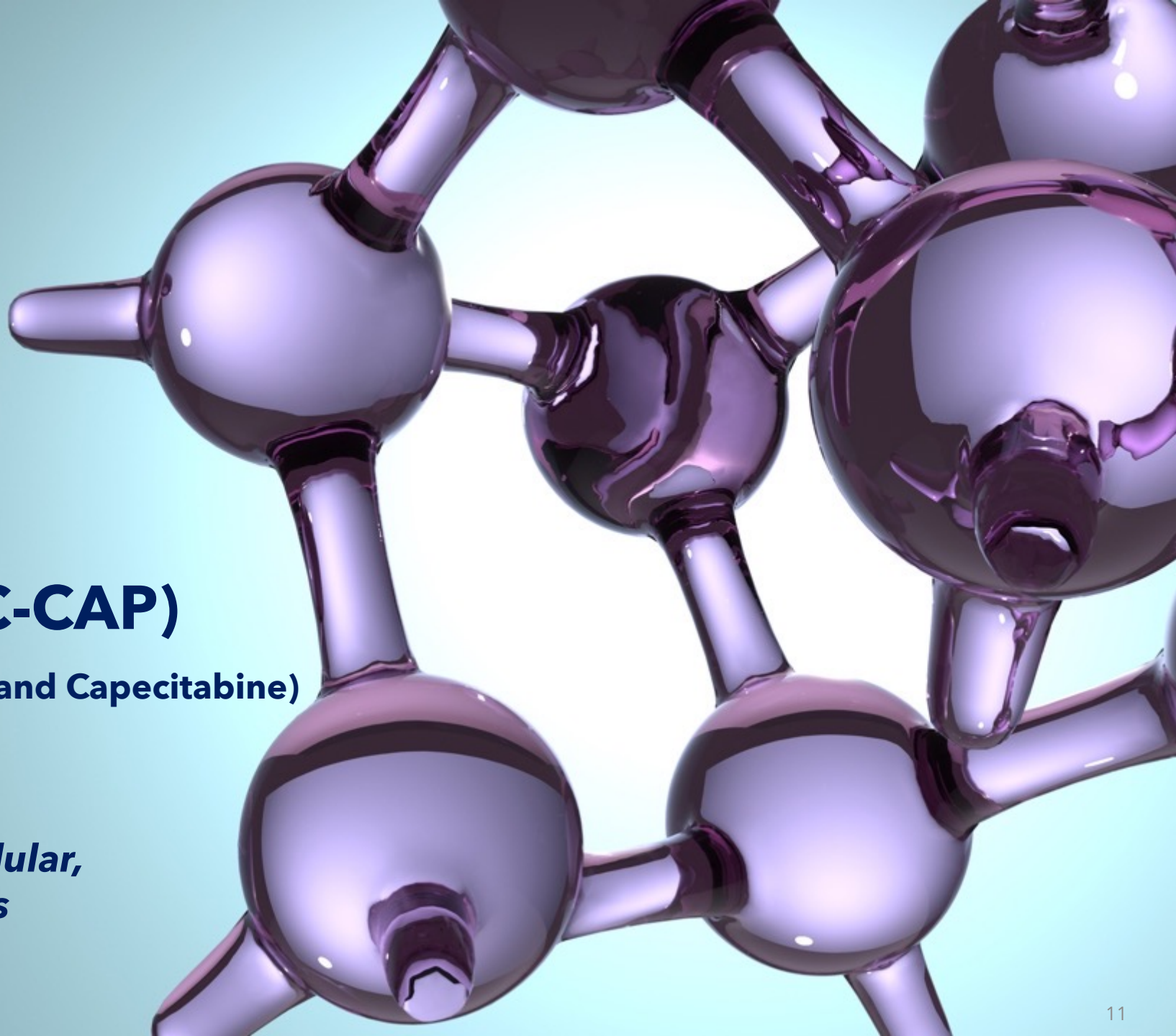


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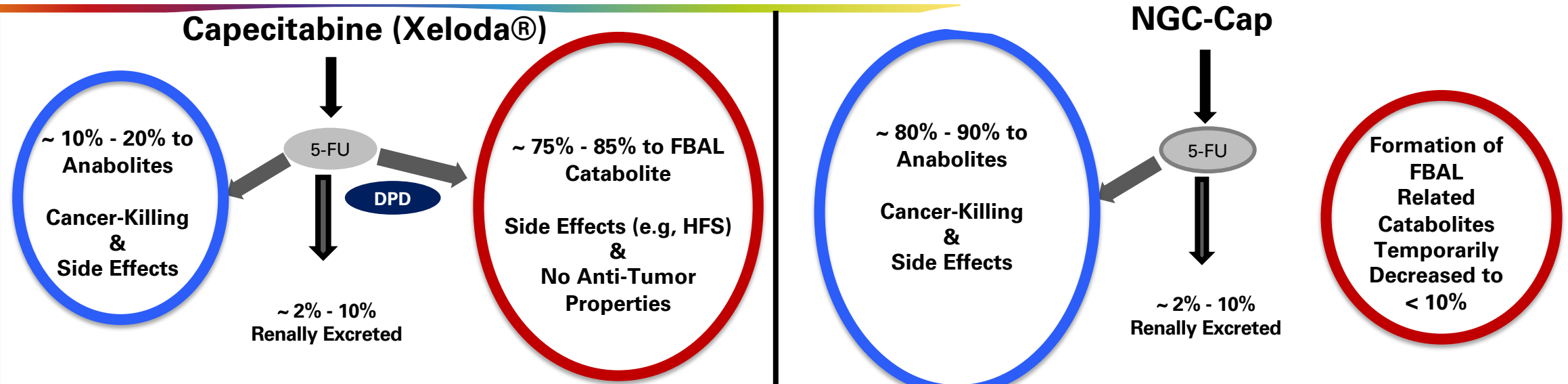
NEXT GENERATION CHEMOTHERAPY CAPECITABINE (NGC-CAP)

(Combination Regimen of PCS6422 and Capecitabine)

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



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



- 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)
- 35% - 70% of patients have dose-limiting side effects from Catabolites (non-cancer killing molecules) requiring a change in therapy

- The mechanism of killing cancer cells is the same as Cap/5-FU
- Formation of Catabolites almost non-existent
- Exposure profile of the cancer cells to cancer-killing Anabolites is GREATER than existing FDA-approved Capecitabine even though the amount of Cap administered is 10% of FDA-Approved Cap
- Therapeutic dose to be determined solely by exposure profile of Anabolites

Highlights of NGC-Cap

	NGC-Cap
Side Effects	<ul style="list-style-type: none">• Fewer Catabolites equals fewer catabolite related side effects in Phase 1b trial• Side effects related to Anabolites in Phase 1b trial even though dose is 5-10% of the typical Cap dose (more efficient cancer cell exposure to Anabolites)
Efficacy	<ul style="list-style-type: none">• Cancer cells exposed to more 5-FU & Anabolites after NGC-Cap
Safety-Efficacy Profile	<ul style="list-style-type: none">• Based on existing communications with FDA, Processa has initiated pre-study start-up tasks for the Project Optimus Phase 2 safety-efficacy optimal dosage regimen trial• Meet with FDA in Dec. on Phase 2 dose (RP2D) and design of Phase 2 trial
Development Commercial	<ul style="list-style-type: none">• More likely to be FDA approved given established MOA and ODR evaluation• More efficient development program than new type of oncology drugs• > 200,000 newly diagnosed patients per year in U.S. have cancers treatable with Cap• U.S. potential annual sales in Cap treated cancer > \$1.0B

Next Milestones of NGC-Cap

Milestone	Approx. Date
Determine Phase 2 Recommended Dose from Ongoing Phase 1b Trial	Ongoing
Phase 2 Trial Preparation (e.g., Writing Protocol, CRO Selection, Site Interviews, Drug Manufacturing)	Ongoing
Meet with FDA to Define Project Optimus Phase 2 Trial Design	Dec 2023
Submit Phase 2 Protocol to IND, Begin Initiating Sites	Mid-2024
Finalize Provisional Patent(s)	2023-2024



Why Processa Now?

- **NGCs provide an improved safety and efficacy profile for FDA-approved cancer-killing molecules allowing more patients to benefit from the NGCs**
- **Each NGC has the potential of annual sales > \$500M-\$1B**
- Upcoming Catalysts/Milestones:
 - PCS6422/NGC-Cap
 - PCS3117/NGC-Gem
 - PCS11T/NGC-Iri
- **New CEO (August 2023) with extensive turnaround, BD track record, and significant oncology experience**
- **Team experienced in oncology and in obtaining FDA approvals in all FDA divisions**
- Potential non-core asset out-licensing transaction(s) to generate non-dilutive



Processa Pharmaceuticals



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Investor & Media Relations:

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