UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 11, 2025

Commission file number 001-39531

PROCESSA PHARMACEUTICALS, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	**45-1539785**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

7380 Coca Cola Drive, Suite 106, Hanover, Maryland 21076
(Address of Principal Executive Offices, Including Zip Code)

(443) 776-3133
(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock: Par value $.0001	PCSA	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation Disclosure.

A copy of a slide presentation (Presentation Materials") that Processa Pharmaceuticals, Inc. ("Processa Pharmaceuticals") intends to publish to its website, is attached to this Current Report on Form 8-K and Exhibit 99.1. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While Processa Pharmaceuticals may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, Processa Pharmaceuticals specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Processa Pharmaceuticals Investor Presentation dated February 2025.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on February 11, 2025.

PROCESSA PHARMACEUTICALS, INC.
Registrant

By: */s/ George Ng*
George Ng
Chief Executive Officer

Exhibit 99.1

Forward-Looking Statement and Disclosures

Processa Pharmaceuticals

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; (ii) our ability to maintain and enforce our intellectual property rights and related license agreements; (iii) our ability to succeed in any current or future litigation; (iv) our ability to successfully implement our strategic plans, including reliance on our lead product candidate; (v) our clinical development and related FDA regulatory approval of product candidates; (vi) clinical results for product candidates and unexpected costs related to applicable clinical development and trials; (vii) our ability to realize value from product candidates and preclinical programs being developed and anticipated to be developed; (viii) our reliance on collaborators and research and development partners; and (ix) our cybersecurity and data privacy.

These and other risks and uncertainties are more fully described in our 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, 2023, as amended, 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 information contained herein, including forward looking statements, to reflect any change in our expectations or any change in events, conditions, or circumstances on which any such statements are based.

About Processa Pharmaceuticals

Processa Pharmaceuticals

De-Risked Strategy for New Cancer Therapy

- Improving the distribution and/or metabolism of existing, proven anti-cancer agents as NCEs
  - Reducing side effects
  - Increasing efficacy
  - Improving potency
- Three anti-cancer NCEs with multiple near-term catalysts
  - Two in clinical development
  - One near clinic-ready
  - All show significantly increased concentration in tumors and decreased concentration in healthy tissues
  - Initial Phase 2 data expected 2H2025
- Experienced team
  - Prior collaboration with FDA to develop multiple FDA Guidances, train FDA reviewers, and develop FDA's Regulatory Science Approach to make regulatory decisions for drug approval
  - >30 indications approved by FDA to date using the teams proprietary Regulatory Science Approach
  - Approach includes defining the optimal dosage regimen using the principles of Project Optimus for Oncology drugs when defining an FDA acceptable benefit-risk profile of efficacy and toxicity

Large Market Opportunity in Oncology

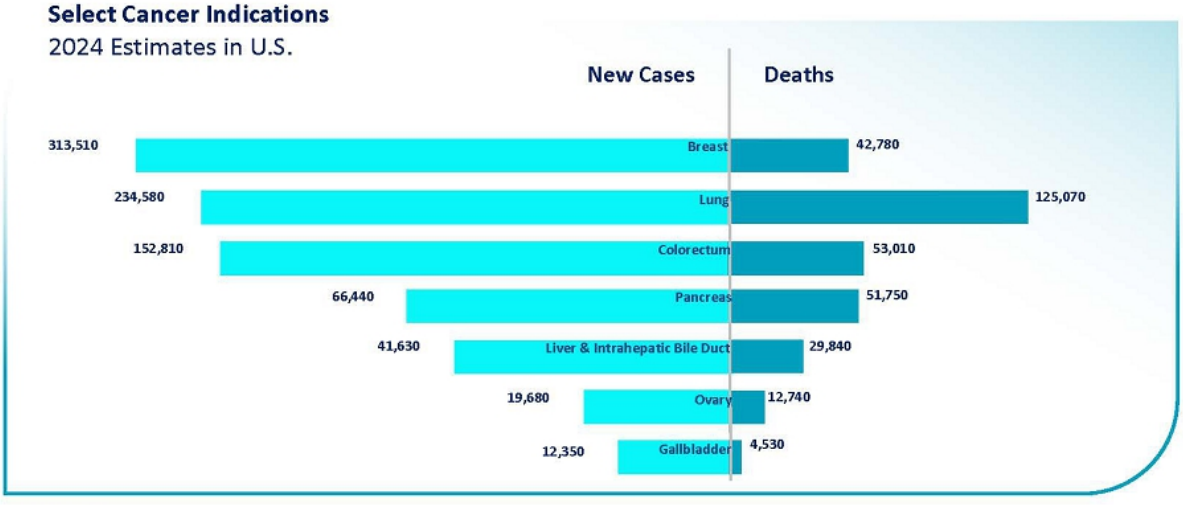
Processa Pharmaceuticals

Cancer is the Second Leading Cause of Death in the U.S.

Two million new cancer cases expected in 2024 and approximately 611,720 deaths

Select Cancer Indications

2024 Estimates in U.S.



American Cancer Society 2024
Colorectum includes appendix
Male and Female breast cancer combined

Our Approach to Next Generation Cancer Therapy (NGC)

Processa Pharmaceuticals

Excellent Risk-Reward: Improving drugs that we know already work

- Industry's approach
  - Search for novel or different ways to treat cancer - exciting, novel technology (gets headlines)
  - High failure rate in clinic and market (often patients fail to complete treatment regimen due to side effects)
- Processa's approach
  - Target heavily used approved drugs where benefit is often limited due to toxicity (e.g., capecitabine, gemcitabine, irinotecan)
  - Improve how the drug metabolizes to its active cancer killing metabolites and/or increases the accumulation of the cancer killing metabolites in the cancer cells
- NGC compounds will potentially improve efficacy and toxicity by altering distribution and/or metabolism of known cancer killing molecules
  - Goal to demonstrate improvement over standard of care
  - Regulatory Science Approach aligns with FDA's Oncology Project Optimus initiative to determine and justify the selection of the ODR[1]
- Improved treatment could expand market to additional patient populations
  - Fewer patients require dose modification, including dose reduction or discontinuation
  - Expanded use in elderly and pediatric patients

[1] https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus

Pipeline

Processa Pharmaceuticals

Improving Safety and Efficacy

Stage of Development

Drug	Target / Indications	Preclinical	Phase 1	Phase 2	Next Milestone
NGC-Cap (PCS6422) ***Capecitabine***	Breast, Colorectal, Hepatocellular, Pancreatic, Gastric, & Other Solid Tumor Cancers			Phase 2 In Process	**2H25:** Interim analysis of Phase 2 trial in advanced or metastatic breast cancer
NGC-Gem (PCS3117) ***Gemcitabine***	Pancreatic, Gall Bladder, Non-Small Cell Lung, & Other Solid Tumor Cancers			Phase 2a Completed	**2025:** Meet with the FDA to define the ODR Phase 2 protocol
NGC-Iri (PCS11T) ***Irinotecan***	Lung, Pancreatic, Ovarian, Colorectal, Gastric, Cervical & Other Cancers	Preclinical			**2025:** Expand preclinical analysis with additional ongoing preclinical efficacy study; Evaluating sites to manufacture PCS11T; Conduct CMC and Pre-IND enabling toxicology studies

NGC-Cap: What Is Capecitabine?

Processa Pharmaceuticals

Commonly Used Anti-cancer Drug with Significant Side Effects

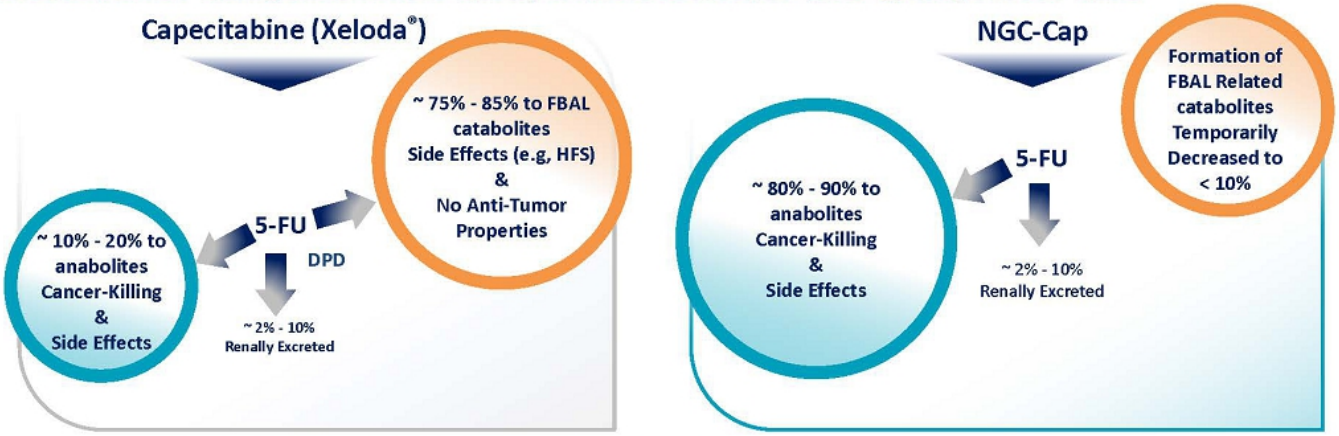
- Capecitabine
  - Oral prodrug of 5-fluorouracil (5-FU)
  - Capecitabine and 5-FU are among the most widely used cancer chemotherapy agents in the treatment of solid tumors such as breast and GI cancer
- Only 20%-40% of patients respond to Capecitabine
- Low treatment response with high side-effect profile
  - Therapeutic dose determined by side effects from catabolites (non-cancer killing molecules) and anabolites (cancer killing molecules)
  - Approximately 35% - 70% of patients have dose-limiting side effects from catabolites requiring a change in therapy
- Medicare dosing units (2021): ~9,200,000

Source: Xeloda product label and Talbot Br J Cancer 86, 1367, 2002.

NGC-Cap: How We Improve Capecitabine Therapy

Processa Pharmaceuticals

Increased cancer-killing anabolites in tumor; Reduced catabolites (side effects) outside tumor



- NGC-Cap is the combination of PCS6422 and Capecitabine
- 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*** Cap even though the amount of Cap administered is 10% of FDA-approved Cap
- Therapeutic dose to be determined solely by exposure profile of anabolites

NGC-Cap: Study Results To Date

Processa Pharmaceuticals

Better Tolerated than Capecitabine with Preliminary Positive Efficacy

Phase 1b Design

- Capecitabine dose escalating 3+3 design with PCS6422 in patients with advanced, relapsed or refractory progressive gastrointestinal cancer
- Evaluated the relationship between the safety-efficacy profile across patients to the systemic exposure of 5-FU and FBAL, as well as the timeline of DPD inhibition
- Determined MTD, Recommended Phase 2 Dose Range (RP2DR), and potential optimal dosage regimens

Results

- 5-10x greater exposure to its 5-FU cancer treatment metabolite than capecitabine
  - Better tolerated than capecitabine even with greater exposure
  - One patient with mild case of hand-foot-syndrome: 6% versus expected ~50% based upon published data
- NGC-Cap demonstrated preliminary anti-tumor activity
  - Positive preliminary efficacy in patients' refractory to other cancer treatments, including 5-FU or capecitabine
  - Partial response or stable disease was observed in 66.7% (8 out of 12) of evaluable patients
  - Progression-free survival was approximately 3 - 11 months in these relapse and refractory patients
- Defined the MTD and RP2DR to be evaluated in Phase 2

NGC-Cap: Phase 2 Study Design

Processa Pharmaceuticals

Based on Discussions with and Recommendations from the FDA

Ongoing Phase 2 clinical trial

- Global multicenter, open-label, adaptive designed trial
  - 60 to 90 patients with advanced or metastatic breast cancer
  - Up to 30 global trial sites
- Evaluating safety-efficacy profile of NGC-Cap versus monotherapy capecitabine
  - Potential optimal dosage regimens defined
  - Personalized medicine approach being reviewed
- Second NGC-Cap regimen may be added if deemed necessary
- Expect to report interim analysis (2H25)

Processa Pharmaceuticals

NGC-Cap Product Profile

Efficacy

- Alters metabolism to increase formation and distribution of 5-FU and cancer-killing molecules to cancer cells while reducing the metabolites that only cause side effects
- Active molecule same as Capecitabine but provides improved treatment

Side Effects

- Better side-effect profile

Intellectual Property

- Current patent protection until 2030; potential patent protection from additional filings until ~2044

Clinical Development

- Recommended Dose Range for Project Optimus evaluation identified in Phase 1b study
- Phase 1b study completed with final data analysis pending
- Ongoing Phase 2 trial treating advanced or metastatic breast cancer with interim readout 2H25

NGC-Gem: What is Gemcitabine?

Standard of care drug with known resistance

- Gemcitabine is widely used in pancreatic, gall bladder, lung, and other solid tumor cancers
- Approximately 20% - 40% of patients respond to Gemcitabine across solid tumor cancers
- Resistance to Gemcitabine a key problem with 55% - 85% of patients inherently resistant or acquire resistance
- Medicare dosing units (2021): ~840,000

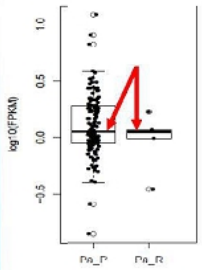
Source: Gemcitabine product label.

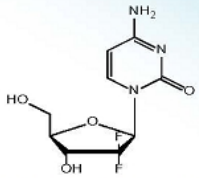
NGC-Gem: Improves Metabolism of Gemcitabine

Processa Pharmaceuticals

Analog of Gemcitabine Metabolized to Active Cancer-Killing Metabolite by Different Route
Patients Resistant to Gemcitabine Have Responded to NGC-Gem

dCK



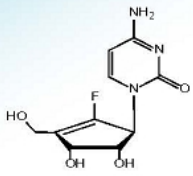


Gemcitabine (dFdC)
IV Administration

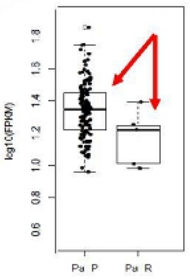
Active Cancer Killing Molecules

In some cancers dCK Expression < UCK2 Expression resulting in metabolism to more cancer-killing molecules for NGC-Gem than Gem

UCK2



NGC-Gem
Oral
Administration

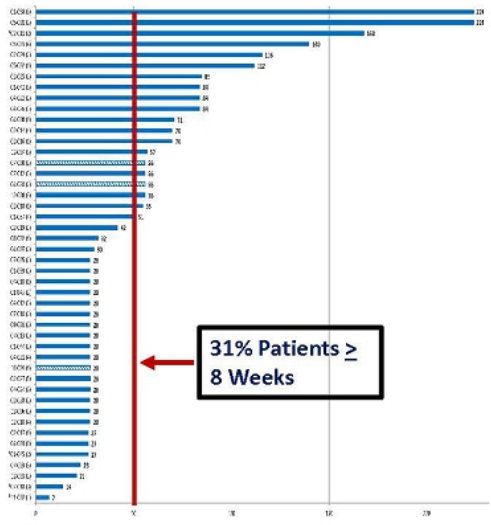


Increase metabolism to cancer-killing molecules given different metabolizing enzyme than Gemcitabine (dCK being one of the major causes for resistance)

NGC-Gem: Phase 2 Safety and Efficacy in Pancreatic Cancer

Processa Pharmaceuticals

Phase 2 Trial in patients with progressive metastatic pancreatic cancer after previous therapies of chemotherapy, including 93% refractory to Gemcitabine



Days on Study

- 31% (14 patients) had progression-free survival for 8 weeks or more
- 12% (5 patients) had stable disease for more than 4 months
- One patient had a tumor reduction of 40% after 28 days of treatment
- Mild to moderate adverse events were reported with a better overall safety profile than Gemcitabine

NGC-Gem Product Profile

Processa Pharmaceuticals

Efficacy

- Positive results demonstrated in Phase 2a trial in pancreatic cancer patients
- Cancer cells exposed to more NGC-Gem cancer-killing molecules due to improved activating enzyme

Side Effects

- Side-effect profile similar to Gemcitabine

Intellectual Property

- Potential patent until 2036

Clinical Development

- Requesting to meet with FDA on the Phase 2 development program, including target population, design of the next safety-efficacy trial, dosage regimen(s), and comparator treatment arm within the trial

NGC-Iri: What is Irinotecan?

Processa Pharmaceuticals

Effective Chemotherapy for Solid Tumors With Black Box Warning

- Irinotecan is widely used in lung, pancreatic, ovarian, cervical & other solid tumor cancers
- Onivyde® is irinotecan in a liposomal formulation
- Approximately 15-35% of patients respond to Irinotecan across the solid tumor cancers
- Major drawbacks are the side-effect profile of irinotecan and Onivyde® including black box warnings for diarrhea and myelosuppression
- Dose limiting side effects result in less patients being able to benefit from treatment
- Medicare dosing units (2021): ~1,800,000

Source: Irinotecan product label.

NGC-Iri: What is NGC-Iri?

Processa Pharmaceuticals

Safer and More Effective Cancer Therapy Without Black Box Warning

- NGC-Iri is a prodrug of SN-38, the active metabolite of irinotecan and Onivyde®
- NGC-Iri preferentially accumulates in the membrane of tumor cells over the membrane of normal cells releasing more SN-38 into the tumor core than irinotecan and Onivyde®

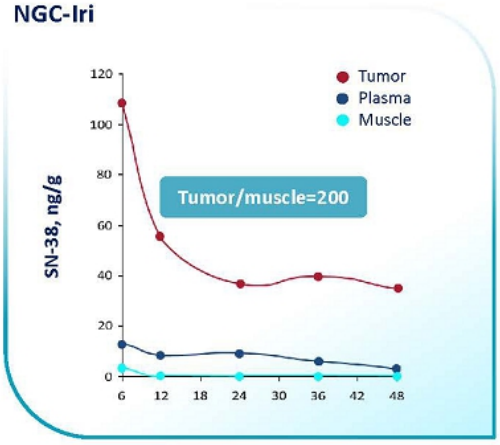
Source: Irinotecan product label.

NGC-Iri: Higher Amounts & Lower Required Dose

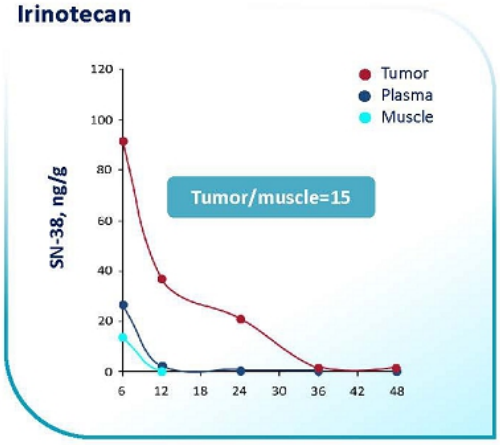
Processa Pharmaceuticals

Tumor-Bearing Mice had 200x Higher Drug in Tumor Versus Muscle Compared to 15x with Irinotecan

NGC-Iri



Irinotecan



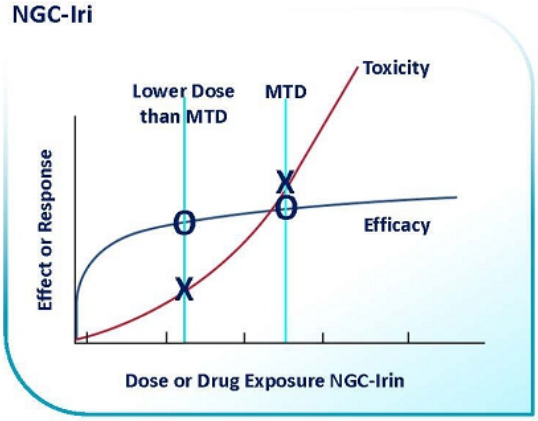
Tissue	NGC-Iri AUC (ng/g*hr)	NGC-Iri Tumor/Tissue Ratio	Irinotecan AUC (ng/g*hr)	Irinotecan Tumor/Tissue Ratio
Tumor	3,855	1	1,153	1
Plasma	403	9.57	172	6.7
Muscle	19.2	200	78	15

NGC-Iri: Higher Amounts & Lower Required Dose

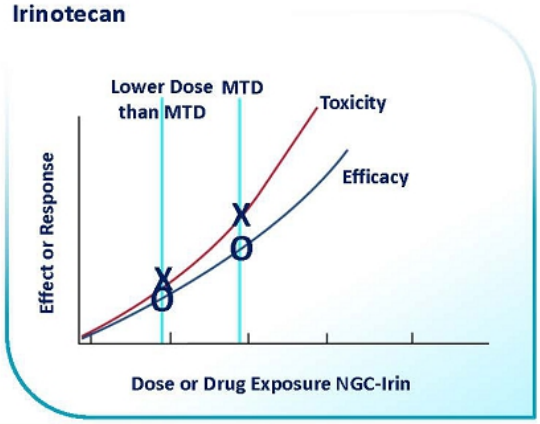
Processa Pharmaceuticals

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

NGC-Iri



Irinotecan



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

NGC-Iri: Comparing NGC-Iri with Irinotecan and Onivyde®

Processa Pharmaceuticals

Supports Potential for a Better Safety Profile with NGC-Iri

- Accumulation of SN-38 in the tumor compared with other tissues was greater after NGC-Iri administration than after irinotecan or Onivyde® administration
  - Tumor-to-muscle ratio of approximately 200 for NGC-Iri and less than 15 for irinotecan and Onivyde®
  - Tumor-to-plasma ratio approximately 10 for NGC-Iri and less than 7 for irinotecan and Onivyde®
- Less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan or Onivyde® administration
  - Muscle-to-plasma ratio being less than 0.10 for NGC-Iri and greater than 0.4 for irinotecan and Onivyde®
- Despite the Black Box warning for severe side effects, in 2021 Medicare reported a total of more than 1.8M doses of irinotecan and Onivyde®

Processa Pharmaceuticals

NGC-Iri Product Profile

Efficacy

- Active molecule SN-38 is same active molecule in Irinotecan
- Distributes SN-38 differently, entering the cell membrane of cancer cells preferentially over normal cells, improving cancer-killing effect

Side Effects

- Given the specificity of NGC-Iri for cancer cells over normal cells, animal data suggests fewer side effects; likely that patients will have less diarrhea and less myelosuppression (a Black Box warning for Irinotecan)

Intellectual Property

- Potential patent protection until 2031; Evaluating potentially new intellectual property

Clinical Development

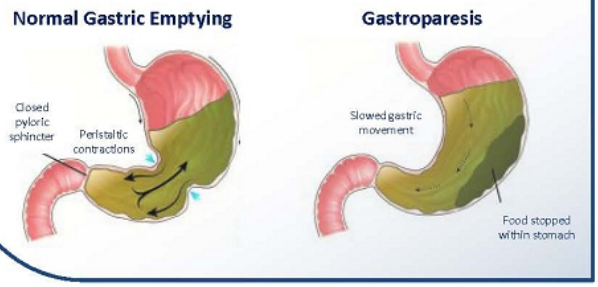
- Expand preclinical analysis with additional ongoing preclinical efficacy study
- Evaluating sites to manufacture PCS11T
- Pre-IND enabling toxicology studies and CMC studies anticipated to be conducted in 2025

Product Partnering Opportunities

Processa Pharmaceuticals

PCS12852 to treat gastroparesis

- Best-in-class 5-HT4 receptor agonist for disease with high unmet medical need
- Completed P2a with positive results showing excellent safety and efficacy profile
- Outstanding safety profile and selectivity combine to provide first meaningful treatment for diabetic gastroparesis patients



PCS499 for rare nephropathies

- Safe and well-tolerated NCE with potential for development on multiple nephropathies
- PCS499 at a suboptimal dose improved proteinuria in a Phase 2 study of non-diabetic nephrotic syndrome, including patients with Primary Glomerular Disease (PGD)
- Significant clinical exposure demonstrating safety benefit to legacy forms of pentoxifylline
- Extensive patent estate
- Potential indications in rare PGDs:
  - Focal segmental glomerulosclerosis (FSGS)
  - Membranous nephropathy (MN)
  - IgA nephropathy (IGAN)

Processa Senior Management

Processa Pharmaceuticals

George Ng
Chief Executive Officer

CALiDi · PENG LIFE SCIENCE VENTURES · SPECTRUM · SCILEX · UNIVERSITY OF NOTRE DAME

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

QUESTCOR · agi · GlobeMax

Sian Bigora, Pharm.D.
Chief Development Officer

QUESTCOR · agi · GlobeMax

Patrick Lin
Chief Business & Strategy Officer

PRIMARIUS CAPITAL LLC · ROBERTSON STEPHENS · E*OFFERING · Kellogg

Russell Skibsted
Chief Financial Officer

Qlimera · ROCKWELL MEDICAL · BIOTIME · SPECTRUM · GE Capital · CLAREMONT MCKENNA COLLEGE · STANFORD BUSINESS

Wendy Guy
Chief Administrative Officer

QUESTCOR · agi · GlobeMax · Mount Wachusett Community College

Track Record of Drug Development with more than 30 FDA approvals

Company Summary

Processa Pharmaceuticals

De-risked strategy to develop more effective cancer therapy options with improved tolerability for cancer patients through an efficient regulatory path

Track record of drug development through regulatory approval using proprietary Regulatory Science Approach

Innovative clinical development programs addressing limitations of standard of care with three active programs

Out-licensing opportunities for non-oncology drug candidates with potential for non-dilutive funding

Processa Pharmaceuticals

Alliance Advisors Investor Relations
Yvonne Briggs
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