March 30, 2023

# Processa Pharmaceuticals Provides Corporate Update and Announces Year End 2022 Financial Results

- **Company focused on the development of Next Generation Chemotherapy drugs in 2023 and out-licensing/business development efforts for non-oncology assets.**
- **Dose escalations continue for Next Generation Capecitabine with no observed adverse events associated with the catabolites of capecitabine.**
- **FDA discussions mid-April on Next Generation Capecitabine Phase 2B trial and overall development following Project Optimus initiative.**

HANOVER, MD., March 30, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a developer of Next Generation Chemotherapy drugs that provide a better safety-efficacy profile than their widely used FDA-approved counterparts, today provided an update on their clinical programs and announced financial results for the year ended December 31, 2022.

Dr. David Young, President and CEO of Processa, commented, “We completed a successful Phase 2A trial of PCS12852 in patients with gastroparesis, positioning the asset well for potential out-licensing or business development opportunities. Today, we are focusing our energy and efforts on the Next Generation Chemotherapies (NGCs) that can reshape the landscape of chemotherapy.

Our first NGC to move into Phase 2B will be Next Generation Capecitabine (NGC-Cap). Since 50-70% of the patients on capecitabine typically have dose-limiting side effects, one major benefit of NGC-Cap is to significantly decrease or potentially eliminate these side effects, so patients do not need to reduce their dose or discontinue treatment entirely. As a safer and potentially more efficacious version of the presently used capecitabine, the target population for NGC-Cap includes patients with such cancers as colorectal, breast, pancreatic, and many other solid tumor cancers. These cancers have more than 200,000 newly diagnosed cases per year in the U.S. We look forward to meeting with the FDA in mid-April to discuss our NGC-Cap Phase 2B trial and hope to initiate the Phase 2B trial in colorectal cancer in the second half of 2023. Given we are working with an approved established cancer-killing molecule, and we will be following the principles of Project Optimus, we anticipate efficiencies in the development of NGC-Cap that we believe will confer better odds of success, while providing better and safer drugs to hundreds of thousands of patients in need of better treatment options.”

**Financial Results for the Year Ended December 31, 2022**

Our cash balance on December 31, 2022, was $6.5 million. Subsequent to year-end, we raised net proceeds of $6.4 million from the sale of 8,432,192 shares of our common stock through a combination of financing vehicles, including a registered direct offering to

accredited investors. Based on our current plans, we believe the cumulative $12.9 million will be adequate to fund our operations into the third quarter of 2024.

Our net loss for the year ended December 31, 2022 was $27.4 million, or $1.70 per share, compared to a net loss of $11.4 million, or $0.75 per share for the same period of 2021. The increase in our net loss was primarily due to a one-time non-cash impairment of an intangible asset for $7.3 million, along with increased stock-based compensation and clinical trial costs.

For the year ended December 31, 2022, we incurred $11.5 million in research and development costs, compared to $6.9 million for the same period in 2021. Our general and administrative expenses totaled $8.8 million for the year ended December 31, 2022 compared to $4.7 million for the same period in 2021. The increase was primarily due to stock-based and other compensation costs. During the year ended December 31, 2022, we allocated $8.8 million of total non-cash compensation costs between our R&D and G&A costs, with the majority being recorded as G&A.

We used cash of $9.6 million during the year ended December 31, 2022 to fund our three clinical trials and operations versus $8.8 million of cash we used in 2021. Our operating cash flow is significantly less than our net loss primarily due to non-cash expenses.

As of March 27, 2022, we had 24.6 million common shares outstanding.

**Conference Call Information**

To participate in this event, please log-on or dial-in approximately 5 to 10 minutes before the beginning of the call.

Date: March 30, 2023
Time: 4:30 p.m. ET
Toll Free: 888-506-0062
International: 973-528-0011
Entry Code: 382258
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/47882

**Conference Call Replay Information**
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 47882
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/47882

**About Processa Pharmaceuticals, Inc.**

The mission of Processa is to develop the Next Generation Chemotherapies (with existing clinical evidence of safety and efficacy) for cancer patients who need better cancer drugs to extend survival and/or improve their quality of life. The Company uses its Regulatory Science Approach and the principles of the FDA's Project Optimus Oncology initiative to provide an efficient development program, increase the probability of approval, and provide a safer and better cancer treatment that can be easily differentiated from what is presently on the market and in development. Processa is developing three Next Generation

Chemotherapy oncology treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat metastatic colorectal, gastrointestinal, breast, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, visit the company's website at[www.processapharma.com](http://www.processapharma.com).

**Forward-Looking Statements**

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements which involve risks and uncertainties. Actual future performance outcomes and results may differ materially from those expressed in forward-looking statements. Please refer to the documents filed by Processa Pharmaceuticals with the SEC, specifically the most recent reports on Forms 10-K and 10-Q, which identify important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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Source: Processa Pharmaceuticals, Inc.