May 12, 2022

Processa Pharmaceuticals Announces First Quarter 2022 Financial Results and Provides Corporate Update

- **Amended Next Generation Capecitabine study has restarted which will elucidate timelines for de novo formation of DPD**
- **Expanded efforts for enrollment in PCS499**
- **PCS12852 on target to complete enrollment by Q3**

HANOVER, Md., May 12, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient's survival and/or quality of life, today announced financial results for the quarter ended March 31, 2022, and provided an update on its clinical programs.

Dr. David Young, CEO and chairman of Processa, commented, "We are on track to get important data from all our clinical programs over the remainder of this year that will elucidate the path to registration for these programs that each have a market that could exceed $1 billion.

- The amended protocol for Next Generation Capecitabine will provide insights into the de novo formation of DPD by mid-summer and allow us to get to the MTD by year-end;

- Our expanded outreach to find and enroll patients in the PCS499 uNL trial has identified new potential patients to complete enrollment for our interim analysis cohort mid-summer and interim results by year-end;

- Enrollment in PCS12852 is going well and is expected to fully enroll patients and provide top line results before the end of the year; and

- We expect to complete the initial development on the macromolecule assays that will be evaluated as potential biomarkers for PCS3117 and confirm our Regulatory Path with FDA by the end of the year."

Financial Results for the Quarter Ended March 31, 2022

We continue to manage our cash efficiently and had a cash balance of $14.4 million at March 31, 2022. We believe this will allow us to complete our three on-going clinical trials and fund our operations into the third quarter of 2023. During the three months ending on March 31, 2022 we spent cash of $1.8 million in our clinical trials and operations.

For the three months ended March 31, 2022, we reported a net loss of $3.2 million, or $0.20 per share compared to a net loss of $2.1 million, or $0.14 per share for the same period of

2021. The increase in our net loss relates primarily to increased clinical trial costs we incurred.

During the three months ended March 31, 2022, we incurred research and development expenses totaling $2.0 million compared to $1.5 million for the same period in 2021. The increase in our R&D expenditures was primarily due to costs we incurred in our active clinical trials. Our general and administrative expenses totaled $1.2 million for the three months ended March 31, 2022 compared to $717 thousand for the same period in 2021. The increase related primarily to increases in non-cash stock-based compensation along with other operating and consulting costs. We allocated $829 thousand of non-cash compensation costs between our R&D and G&A expenses.

As of March 31, 2022, we had 15.8 million shares of common stock 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: May 12, 2022
Time: 4:30 p.m. ET
Toll Free: 877-545-0320
International: 973-528-0002
Entry Code: 896576
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/45432

Conference Call Replay Information
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 45432
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/45432

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: Next Generation Capecitabine (formerly identified as PCS6422) for metastatic colorectal cancer and breast cancer, PCS499 for ulcerative necrobiosis lipoidica and PCS12852 for gastroparesis. The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's website at 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.

For More Information:
Michael Floyd
mfloyd@processapharma.com
(301)651-4256

Patrick Lin
(925) 683-3218
plin@processapharma.com

Processa Pharmaceuticals

Source: Processa Pharmaceuticals, Inc.