November 11, 2021

# Processa Pharmaceuticals Announces Third Quarter 2021 Results and Provides Corporate Update

*Clinical Drug Pipeline is Funded and Targeting Major Milestones mid-2022*

HANOVER, Md., Nov. 11, 2021 (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 announces financial results for the quarter ended September 30, 2021, and provides a corporate update.

Dr. David Young, CEO and Chairman of Processa, commented, "During the first three quarters we made substantial progress advancing our three clinical drugs, each having a potential market exceeding $1 billion. We initiated and commenced enrollment in both PCS499 and PCS6422 ("Next Generation Capecitabine") and received a Safe to Proceed letter from FDA for the PCS12852 IND. We recently reported results confirming our hypothesis that inhibiting DPD produced significantly lower levels of FBAL and demonstrated 50 times greater exposure than reported for FDA approved capecitabine. We are amending the protocol in the PCS6422 study to ascertain a more precise understanding of DPD in the presence of capecitabine and expect these insights to dramatically improve the safety and efficacy of one of the cornerstones of chemotherapy.

While we have experienced slower than expected enrollment in PCS499 and currently have three patients in the trial, we are expanding our efforts and outreach to identify new patients, and still anticipate completing the trial in 2022."

**Recent Highlights and New Developments**

- The Next Generation Capecitabine Phase 1B trial confirmed our hypothesis and provided insight into the importance of obtaining greater clarity on DPD inhibition and de novo formation, which could possibly lead to a personalized or precision medicine approach to treating cancer patients.
- We received clearance from FDA to proceed with a Phase 2A trial for the treatment of Gastroparesis and anticipate enrolling the first patient in the first half of 2022 and complete the conduct of the trial in 2022.
- We are conducting a critical review of our clinical assets to assess opportunities to accelerate development and approval timelines.

**Financial Results for the third quarter of 2021**

Our cash and cash equivalents totaled $19.1 million as of September 30, 2021, compared to $15.4 million as of December 31, 2020. We had 15.7 million shares of common stock outstanding as of November 2, 2021.

Our research and development expenses for the three months ended September 30, 2021 were $1.7 million compared to $533 thousand for the same period in 2020. General and administrative expenses for the three months ended September 30, 2021 were $1.3 million compared to $423 thousand for the same period in 2020. We reported a net loss for the three months ended September 30, 2021 of $3.0 million compared to a net loss for the comparable prior year period of $3.1 million. Our net loss per share for the three months ended September 30, 2021 was $0.19 compared to net loss per share for the three months ended September 30, 2020 of $0.55.

During the three months ended September 30, 2021 we incurred $51 thousand of final expense related to our licensing of PCS3117 in June 2021. During the comparable period of 2020 we incurred $2.0 million of non-cash expenses related to our licensing of PCS12852.

**Conference Call Information**

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

Date: November 11, 2021
Time: 5:30 PM
Toll-Free: 1-855-327-6838 Toll / International: 1-604-235-2082 Conference ID: 10016982

The conference call will also be available via a live, listen-only webcast and can be accessed through the Investor Relations section of Processa Pharmaceuticals website at: https://processapharmaceuticals.com/

**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: PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/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 registration statement relating to the securities being sold in this offering, which identifies important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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