May 13, 2021

Processa Pharmaceuticals Announces First Quarter 2021 Results and Provides Corporate Update

Clinical drug pipeline is funded and targeting major milestones in Q2 and 2H 2021

HANOVER, Md., May 13, 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 year ended March 31, 2021, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "During the first quarter we made substantial progress advancing our three clinical in-licensed drugs, each with a potential market exceeding $1 billion. We expect first patients to be dosed with PCS6422 and PCS499 within the next six weeks, and to receive interim data for PCS6422 near the end of the third quarter of 2021 and interim data for PCS499 during the first quarter of 2022."

Recent Highlights and New Developments

- We have selected 5 U.S. clinical sites to enroll patients with ulcerative necrobiosis lipoidica and started the screening process for our first patient in our Phase 2B trial "A Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of PCS499 in Treating Ulcerations in Patients who Have Necrobiosis Lipoidica." In order to expedite enrollment for this rare condition, we are evaluating additional clinical sites both within and outside the U.S.

- We are initiating clinical sites to enroll patients into our Phase 1B trial "A Study of the Safety and PK of PCS6422 (Eniluracil) with Capecitabine in Patients with Advanced, Refractory GI Tract Tumors."

- We have received guidance from the FDA and plan to submit an IND application in the third quarter of 2021. PCS12852 is a small molecule drug in development for the treatment of gastroparesis and functional gastrointestinal motility disorders.

- In February 2021, we closed a private placement with institutional and accredited investors for gross proceeds of $10.2 million. We sold 1,321,132 shares of the common stock at a purchase price of $7.75 per share and received net proceeds of $9.9 million.

Upcoming Clinical Drug Development Milestones

First half of 2021

- Dose our first patient in our PCS499 (Ulcerative NL) Phase 2B trial.
- Dose our first patient in our PCS6422 (cancer) Phase 1B trial.

Second half of 2021

- Submit our IND application for PCS12852 in Gastroparesis to FDA.
- Begin our interim cohort results for PCS6422.

First half of 2022

• Obtain interim results from our PCS499 Phase 2B trial.
• Dose our first patient in a Phase 2A trial for PCS12852.

Financial Results for the first quarter of 2021

Our cash and cash equivalents totaled $23 million as of March 31, 2021, compared to $15.4 million as of December 31, 2020. We had 15.5 million shares of common stock outstanding as of March 31, 2021.

Our research and development expenses for the three months ended March 31, 2021 were $1.5 million compared to $501 thousand for the three months ended March 31, 2020. General and administrative expenses for the three months ended March 31, 2021 were $717 thousand compared to $484 thousand for the three months ended March 31, 2020. We reported a net loss for the three months ended March 31, 2021 of $2.1 million compared to a net loss for the comparable prior year period of $874 thousand. Our net loss per share for the three months ended March 31, 2021 was $0.14 compared to net loss per share for the three months ended March 31, 2020 of $0.16.

Conference Call Information

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

Date: May 13, 2021
Time: 5:30 p.m. ET
Toll Free: 888-506-0062; Entry Code: 396394
International: 973-528-0011; Entry Code: 396394
Live Webcast: **https://www.webcaster4.com/Webcast/Page/2572/41274**

Conference Call Replay Information
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 41274
Replay Webcast: **https://www.webcaster4.com/Webcast/Page/2572/41274**

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 well-defined criteria to select drugs for its pipeline in order to achieve high-value milestones effectively and efficiently. Active

pipeline programs include: PCS499 (ulcerative necrobiosis lipoidica), PCS12852 (GI motility/gastroparesis) and PCS6422 (metastatic colorectal cancer and breast cancer). 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 press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that reflect the current beliefs, expectations and assumptions of the "Company regarding the future of the Company's business, our future plans and strategies, regulatory approvals, clinical results, future financial condition and other future conditions. All statements other than statements of historical facts contained in this press release, including expressed or implied statements regarding future results of operations and financial position, business strategy, product candidates, regulatory approvals, expected research and development costs, planned preclinical studies and clinical trials, expected results of clinical trials, and their timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. The words "if approved," "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include information about qualitative assessments of available data, potential benefits, expectations for clinical trials, and anticipated timing of clinical trial readouts and regulatory submissions. This information involves risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, including the impact of the COVID-19 pandemic on our business, operations, and regulatory and clinical development timelines, plans and expectations, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary and interim data, including the possibility of unfavorable new clinical trial data and further analyses of existing clinical trial data; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities. These and other risks and uncertainties are more fully described in our periodic filings with the Securities and Exchange Commission ("SEC"), including the risk factors described in the section entitled "Risk Factors" in the quarterly and annual reports that we file with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. Except as required by law, we assume no obligation to update forward-looking statements contained in this press release whether as a result of new information, future events, or otherwise, after the date of this press release.

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

James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

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