Processa Pharmaceuticals Announces Second Quarter 2021 Results and Provides Corporate Update

Adds fourth clinical asset, RX-3117, and targets major milestones in the second half of 2021

HANOVER, Md. -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a clinical stage biopharmaceutical company developing drugs to improve the survival and/or quality of life for patients who have an unmet medical need condition, announces today financial results for the quarter ended June 30, 2021, and provides corporate update.

Dr. David Young, CEO and chairman of Processa, commented, "During the second quarter we made significant progress advancing our clinical programs, in-licensed another clinical asset - RX-3117 – and will have four clinical programs with addressable markets of $500 million to $1.5 billion. Looking at upcoming milestones, we have begun to develop the biomarker assays for 3117 in pancreatic cancer patients with the expectation that the assay validation will be completed in the first half of 2022. We also anticipate filing an IND in September for PCS12852 with site initiation beginning before year end. Additionally, we expect interim data for PCS6422 in the fourth quarter of 2021 and interim data for PCS499 during the first half of 2022. Taken altogether, we see a consistent cadence of upcoming catalysts and tremendous amount of near-term value creation."

Recent Highlights and New Developments

- Dosed our first two patients in the PCS499 Phase 2B ulcerative Necrobiosis Lipoidica (NL) trial. NL is a rare, chronic, idiopathic, granulomatous disease that can significantly effect a patient's quality of life and is caused by a number of diverse pathophysiological changes in a patient. There are no approved treatments for NL or ulcerative NL and no acceptable standard of care. Approximately 30% of NL patients have the ulcerative form of NL.

- Dosed our first patient in our Phase 1B trial evaluating the safety and PK of PCS6422 and capecitabine when administered to patients with advanced, refractory GI cancer. The combination of PCS6422 and capecitabine is expected

to improve the benefit-risk profile of capecitabine by improving capecitabine safety and/or efficacy.

- Licensed in PCS3117 (formerly RX-3117), an oral, anticancer agent with an improved pharmacological profile relative to gemcitabine. PCS3117 has a family of patents extending into 2036 as well as U.S. Food and Drug Administration (FDA) Orphan Designation for the treatment of Pancreatic Cancer. Processa has begun to develop biomarkers assays to better predict which patients with pancreatic or non-small cell lung cancer are more likely to benefit from PCS3117 over gemcitabine and other chemotherapeutic agents.

- Joined the Russell Microcap ®, resulting in automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

Upcoming Clinical Drug Development Milestones

Second half of 2021

- Complete enrollment of 8-10 patients for the PCS499 Phase 2B interim analysis
- Submit PCS12852 IND application to FDA for Gastroparesis and initiate sites
- Begin assay development of biomarkers for PCS3117 in pancreatic cancer
- Complete interim analysis of PCS6422 Phase 1B trial in GI cancer

2022

- Interim analysis of PCS499 Phase 2B trial in ulcerative NL
- Final analysis of PCS499 Phase 2B trial in ulcerative NL
- Enroll and complete PCS12852 Phase 2A gastroparesis trial
- Complete assay validation of biomarkers for PCS3117 and initiate sites for Phase 2B pancreatic cancer trial
- Determine the maximum tolerated dose for capecitabine in the PCS6422-capecitabine combination Phase 1B GI cancer trial

Financial Results for the second quarter of 2021

Our cash and cash equivalents totaled $20.8 million as of June 30, 2021, compared to $15.4 million as of December 31, 2020 and we had 15.6 million shares of common stock outstanding as of August 2, 2021.

Our research and development expenses for the three months ended June 30, 2021 were $1.6 million compared to $427 thousand for the three months ended June 30, 2020. General and administrative expenses for the three months ended June 30, 2021 were $1.3 million compared to $375 thousand for the three months ended June 30, 2020. Our total stock-based compensation included in general and administrative expenses for the three months ended June 30, 2021 was $674 thousand compared to $87 thousand for the three months ended June 30, 2020. We reported a net loss for the three months ended June 30, 2021 of $3.2 million compared to a net loss for the comparable prior year period of $733 thousand. Our net loss per share for the three months ended June 30, 2021 was $0.20 compared to net loss per share for the three months ended June 30, 2020 of $0.13.

Conference Call Information

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

Date: August 12, 2021
Time: 5:30 p.m. ET
Toll Free: 888-506-0062; Entry Code: 628453
International: 973-528-0011; Entry Code: 628453
Live Webcast: https://www.webcaster4.com/Webcast/Page/2572/42137

Conference Call Replay Information
Toll-free: 877-481-4010
International: 919-882-2331
Replay Passcode: 42137
Replay Webcast: https://www.webcaster4.com/Webcast/Page/2572/42137

About Processa Pharmaceuticals, Inc.

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions. We are a development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options than presently exist for their medical condition. To

increase the probability of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties has been shown to be effective in the population. We currently have three drugs in various stages of clinical development: PCS499 for Ulcerative Necrobiosis in Phase 2B; PCS3117 for metastatic pancreatic cancer and non-small cell lung cancer in Phase 2B; and PCS6422 for metastatic colorectal cancer and breast cancer in Phase 1B. The PCS12852 IND for the treatment of gastroparesis will be submitted in the third quarter of 2021. For more information, visit the company's website at www.ProcessaPharma.com.

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