September 15, 2022

Processa Pharmaceuticals Provides Update on Enrollment Across all Clinical Programs

- PCS12852 for Gastroparesis concluded enrollment a month ahead of schedule. Statistics on gastric emptying, safety and GEBT data will be available by the end of October and full topline data is expected before year end.
- New site added for PCS6422 to accelerate enrollment, important data on de novo formation of DPD in October.
- New sites added and new geographic areas for PCS499.
- Efforts to create awareness of trials have had a positive effect on our enrollment across clinical programs.

HANOVER, MD, Sept. 15, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), ("Processa" or "Company"), a clinical stage biopharmaceutical company focused on developing products to improve survival and/or quality of life for patients who have an unmet medical need condition for which there are few or no therapeutic options, today provided an update on enrollment across all its clinical programs.

"Recruiting for studies of very rare diseases like ulcerative Necrobiosis Lipoidica can be challenging. We are encouraged by the results of our multi-faceted campaigns to increase the awareness and opportunities for patients to participate in our trial and are hopeful that these will continue to increase the number of patients in screening and enrollment. We have seen an increased willingness of patients to travel, potentially due to lower concerns about COVID" said Sian Bigora, Processa's Chief Development Officer.

"We are also very encouraged by the rapid enrollment in PCS12852. This reminds us of the extraordinarily limited treatment options for gastroparesis and that patients are looking for alternative options to treat this condition. We continue to advance our clinical programs and with the expectation of important data from these programs in late 2022, each program will move further in the clinical development towards NDA submissions".

PCS12852

The Company is pleased to announce completion of enrollment of our PCS12852 Phase 2A trial in moderate to severe gastroparesis ahead of its original expectations. This will allow it to release gastric emptying and efficacy/safety data and topline data by the end of 2022. This Phase 2A trial is a placebo-controlled, randomized, dose response study designed to evaluate the safety, pharmacokinetics and efficacy of PCS12852 on the gastric emptying rate as assessed by 13C Spirulina GEBT in patients with moderate to severe gastroparesis. Data collected from this study will be used to design the larger Phase 2b study that is expected to be initiated in 2023.

PCS12852 is a novel, potent, and highly selective 5-HT4 receptor agonist for treating

Gastrointestinal (GI) mobility disorders. These GI disorders may take many forms, including chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia, and gastroparesis.

Other 5-HT4 receptor antagonists have been successful in treating GI motility disorders. However, these often have less 5-HT4 selectivity and are associated with cardiovascular side effects due to the drugs binding to other receptors. In contrast, PCS12852 has been shown in clinical trials to increase GI function with no reported serious adverse effects. Other currently approved options for the treatment of gastroparesis have black box warnings and/or limited due to in adverse events.

PCS6422

The enrollment for PCS6422 Next Generation Capecitabine (combination drug with of Capecitabine) Phase 1B trial in gastrointestinal cancer has successfully re-started after modifications were made to the protocol to better understand the effect of various PCS6422 dosage regimens on the irreversible inhibition of DPD, de novo formation of DPD, and the new safety profile of capecitabine when administered with PCS6422. Data from the study is expected in late 2022 with determination of the maximum tolerated dose in early 2023.

The Company anticipates complete enrollment of the next cohort and the evaluation of the inhibition & de novo formation timeline for the DPD Enzyme in the last quarter of 2022. Determination of the maximum tolerated dose followed by the design and initiation of the Phase 2B/3 trial is expected in 2023. The ongoing Phase 1B trial is a multi-center, maximum tolerated dose trial in patients with advanced, refractory gastrointestinal cancer. The trial is designed to evaluate the change in the metabolism of 5-FU when DPD has been inhibited, provide for an understanding of the de novo formation of DPD in the presence of 5FU, and given the increased potency of capecitabine, the MTD of Next Generation Capecitabine.

Capecitabine, one of the most widely used chemotherapy agents in oncology, is an oral prodrug of 5-FU that converts to 5-FU. Approximately 80% of 5-FU is metabolized through catabolism to non-cancer killing metabolites that may cause dose-limiting side effects such as hand-foot syndrome and cardiotoxicity while only 20% of 5-FU is metabolized to active nucleotides which actually kill cancer cells. Given the catabolism is initialized through the DPD enzyme, PCS6422 (an irreversible inhibitor of DPD) decreases the catabolism of 5-FU resulting in more of the 5-FU being metabolized to active 5-FU nucleotides. Combining PCS6422 with capecitabine results in lower amounts of capecitabine needed to cause cell death, making the PCS6422-capecitabine combination a more potent and potentially better and safer treatment option.

PCS499

The Company has expanded its efforts to make patients with ulcerative Necrobiosis Lipoidica more aware of its ongoing Phase 2B PCS499 trial, including opening additional trial sites. Through these efforts, and what it believes to be a lessening COVID concern, the Company has noted increased inquiries related to its trial, resulting in an increase in pre-screening efforts. Management anticipates these efforts will lead to additional patients enrolling in the trial allowing the Company to complete its interim analysis in 2023.

PCS499 is a deuterated analog of a major metabolite of pentoxifylline (PTX or Trental®).

PCS499 and its active metabolites have a diverse pharmacology profile and can act on multiple targets that play vital roles in the treatment of various conditions. Investigators postulate that PCS499 may provide a novel treatment solution for ulcerated Necrobiosis Lipoidica, due to its ability to impact many of the biological pathways that contribute to the physiological processes associated with the disease. *For more information on the clinical study of PCS499, please visit https://necrobiosislipoidicastudy.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 Next Generation Capecitabine PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/gastroparesis). For more information, visit our 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.

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