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Processa Pharmaceuticals Announces First Patient Enrolled in the PCS12852 Phase 2A Trial for the Treatment of Gastroparesis

- **Study will advance understanding of proper dosing while providing data to assist in the design of the next study for this >$1B market**
- **Expect top line data at the end of 2022**

HANOVER, MD, April 05, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (NASDAQ: PCSA), ("Processa" or the "Company"), a clinical-stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have an unmet medical need, announced today that it has enrolled its first patient in the Phase 2A clinical trial of PCS12852 in patients with moderate to severe gastroparesis. Gastroparesis is a chronic gastric motility disorder in which the stomach does not empty food as quickly as it should, resulting in potentially serious forms of heartburn, nausea, vomiting, and bloating for millions of patients in the U.S. As such gastroparesis is recognized to be a serious unmet medical need condition for which patients need alternative treatment options.

Currently, the only FDA approved pharmaceutical treatment for gastroparesis is metoclopramide, a dopamine D2 receptor antagonist, which is approved only for diabetic gastroparesis, not for other subsets of gastroparesis. Additionally, it carries a black box warning, limiting use for this chronic disorder to less than 12 weeks due to potentially serious side effects.

PCS12852 is a novel, potent, and highly selective 5-hydroxytryptamine-4 (5-HT4) receptor agonist. Although 5-HT4 receptor agonists have been effective for the treatment of gastroparesis in the past, the nonselective binding to other 5HT receptors has resulted in serious side effects and lack of use in gastroparesis patients. PCS12852 differs from other 5HT4 agonists because it has greater potency and is a more selective 5-HT4 agonist with a binding affinity to the 5-HT4 receptor being 200-fold times the affinity for other 5-HT receptors. Furthermore, preclinical and clinical studies with PCS12852 have shown minimal side effects at the effective dose.

"We are very pleased to announce that we have randomized the first patient in our PCS12852 Phase 2A study for the treatment of patients with gastroparesis, " said Dr. Sian Bigora, Chief Development Officer at Processa, "In our previous Phase 2A clinical study in constipation patients, the gastric emptying rate significantly improved while on PCS12852 with no safety concerns. We expect this study to show a similar effect on the gastric emptying rate as well as provide us with valuable data on the effect of PCS12852 on the symptoms associated with gastroparesis in both diabetic and idiopathic gastroparesis

patients. Information from the study will then be used to further design our Phase 2B study."

The study is entitled, "A Phase 2A, Placebo-controlled, Randomized, Dose Response Study of the Safety, Pharmacokinetics and Efficacy of PCS12852 on Gastric Emptying Rate Assessed by 13C Spirulina Gastric Emptying Breath Test (GEBT) in Patients with Moderate to Severe Gastroparesis" and will be conducted in approximately twenty-four (24) patients in up to eight centers in the United States. (NCT05270460)

About Gastroparesis

Gastroparesis is a disorder characterized by delayed gastric emptying of solid food in the absence of a mechanical obstruction, particularly pyloric stenosis. This delay may result in the cardinal symptoms of early satiety, postprandial fullness, nausea, vomiting, belching, bloating, and pain. Gastroparesis can be idiopathic, associated with diabetes mellitus, can occur after a medical intervention (iatrogenic or post-surgical), may be associated with neurological disorders, or may occur after a bacterial or viral infection. Although there have been advances in understanding the mechanisms and pathophysiology of gastroparesis, there are still significant gaps in knowledge, inconsistencies across studies, and potential differences between different etiological groups (e.g., diabetic versus idiopathic). Gastroparesis is associated with significantly lower survival. In addition to its effect on mortality, gastroparesis symptoms negatively impact the quality of life and day-to-day functioning of patients. With the limitation on currently approved treatments for gastroparesis, there still is a need for new, effective treatments for this disorder.

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 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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