Processa Pharmaceuticals Cleared by FDA to Proceed with Phase 2a Trial for the Treatment of Gastroparesis

HANOVER, MD -- October 12, 2021 -- 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 unmet medical needs, announced today that they have been cleared by the U.S. Food and Drug Administration (FDA) to proceed with a Phase 2a clinical trial of PCS12852 in patients with moderate to severe gastroparesis, an unmet medical need condition for which patients need alternative, safer treatment options.

The only FDA-approved drug to treat gastroparesis is metoclopramide, a dopamine D2 receptor antagonist that has serious side effects and can only be used as a short-term treatment. PCS12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat gastrointestinal (GI) motility disorders such as chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia, and gastroparesis. However, these less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved for gastroparesis. The side effects associated with the off-target receptor binding (e.g., cardiovascular side effects) of these 5-HT4 agonists, especially the binding on 5-HT receptors other than 5-HT4, has limited their use in gastroparesis and other conditions. Given the off-target receptor binding of PCS12852 is minimal, no cardiovascular side effects have been associated with PCS12852 in non-clinical toxicology studies at concentrations as high as 1,000 times the maximum concentration observed in humans, making PCS12852 a potentially safe treatment option for gastroparesis and other GI motility disorders.

"This decision by the FDA is an important milestone in the clinical development program for PCS12852," said Dr. David Young, CEO and Chairman of Processa, "We have clinical data demonstrating that PCS12852 improves the gastric emptying rate in patients with functional constipation. Our IND will allow us to demonstrate that PCS12852 also improves the gastric emptying in gastroparesis patients, a market estimated to be as much as $1.6 Billion. We expect to ramp up our Phase 2a gastroparesis trial over the next few months and have our first patient dosed in Q1-2022."

The Phase 2a 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 up to eight centers in the Unites States.

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. Gastroparesis is a disease that can significantly impact the quality of life for 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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