November 8, 2022

Processa Pharmaceuticals

PCS12852 Improves Gastric Emptying in Gastroparesis Patients

- In a Phase 2A Proof-of-Concept trial, the Gastric Emptying Breath Test (GEBT) results demonstrated statistical improvement in gastric emptying in gastroparesis patients receiving 0.5 mg of PCS12852 (6 patients) as compared to placebo (8 patients) at a $p < 0.10$ level.
- Adverse events associated with this Phase 2A trial were mild to moderate with no clinically significant cardiovascular or serious adverse events.
- Evaluation of the effect of PCS12852 on gastroparesis symptoms is expected before the end of this year.
- Processa plans to initiate a Phase 2B trial in 2023.

HANOVER, MD, Nov. 08, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA), a diversified clinical-stage company developing products to improve survival and/or the quality of life for patients who have an unmet medical need condition, announces positive gastric emptying results from its PCS12852 Phase 2A trial in patients with moderate to severe gastroparesis. This Phase 2A trial was a 4-week placebo-controlled, randomized, dose-response trial designed to evaluate the effect of PCS12852 on gastric emptying, safety, pharmacokinetics, and gastroparesis symptoms. Two dosage regimens of PCS12852 versus placebo were evaluated in patients with moderate to severe gastroparesis.

PCS12852 is a novel, potent, and highly selective 5-hydroxytryptamine-4 (5-HT4) receptor agonist. While there are other 5-HT4 receptor agonists used to treat gastrointestinal (GI) motility disorders, these have less 5-HT4 selectivity and are associated with serious cardiovascular side effects due to the binding to other receptors. Although 2-5 million patients have moderate to severe chronic gastroparesis in the U.S., the only FDA-approved treatment options for gastroparesis have black box warnings and can only be used for 12 weeks due to adverse events.

In contrast, PCS12852 has been shown in normal healthy volunteers and constipation patients to increase GI function with no cardiovascular and no serious adverse effects. Adverse events associated with this Phase 2A trial were mild to moderate, occurring within the first few days after starting treatment, and quickly resolved without any sequelae. There were no clinically significant cardiovascular, unexpected, or serious adverse events (SAEs) reported during the study.

Since the gastric emptying rate in gastroparesis patients is known to be delayed, the gastric emptying rate in the Phase 2A study was assessed using the Cairn Diagnostic ^{13}C Spirulina Gastric Emptying Breath Test (GEBT), which is an FDA-approved diagnostic tool used for measuring the rate of solid-phase gastric emptying and for identifying delayed gastric emptying. The gastric emptying rate half time (t_{50}), as measured by the GEBT from baseline to Day 28, was calculated for each patient.

GEBT results from this small Phase 2A Proof-of-Concept study, which included a total of 14 patients in the 0.5 mg (6 patients) and placebo (8 patients) groups, demonstrated statistical improvement in gastric emptying in patients receiving 0.5 mg of PCS12852 as compared to placebo at a $p < 0.10$ level. The mean (±SD) t_{50} change from baseline was decreased for 0.5 mg PCS12852 compared with placebo by -31.90 ± 50.53 min vs -9.36 ±42.43 min, respectively. Differences were not observed between the placebo and the 0.1 mg dose.

“We are pleased that this first Phase 2A study with PCS12852 was able to demonstrate a prokinetic effect and improve gastric emptying in gastroparesis patients,” said Dr. Sian Bigora, Chief Development Officer at Processa. “The data from this study will inform the design of our planned Phase 2B study. Gastroparesis continues to be a serious disease that has unmet needs, and we are hopeful that PCS12852 will ultimately help improve the quality of life of gastroparesis patients.”

About Gastroparesis

Gastroparesis is a disorder characterized by delayed gastric emptying of solid food in the absence of 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 the millions of patients with 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 its Regulatory Science Approach criteria when selecting drugs for development in order to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: PCS6422 (metastatic colorectal cancer, breast cancer), PCS12852 (gastroparesis, functional constipation), and PCS499 (ulcerative necrobiosis lipoidica). Members of the Processa development team have been involved with more than 30 approvals for indications in almost every division of the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit our website at www.processapharma.com.

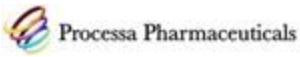
Forward-Looking Statements

This release contains forward-looking statements. The statements in this press release that are not purely historical are forward-looking statements that 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.

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

Patrick Lin
(925) 683-3218
plin@processapharma.com



Source: Processa Pharmaceuticals, Inc.