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Processa Pharmaceuticals

Processa Pharmaceuticals Announces PCS12852 Successfully Improves the Clinical Symptoms Associated with Gastroparesis in Phase 2A Trial

- A 0.5 mg daily dose of PCS12852 administered over 28 days in gastroparesis patients successfully improved gastroparesis symptoms in a clinically meaningful way as defined by greater than a 0.5 reduction in the ANMS GCSI-DD score compared to baseline.
- The percentage of patients who met the clinically meaningful change in symptom score was greater in the PCS12852 0.5 mg daily dose group than in the placebo or the PCS12852 0.1 mg daily dose groups.
- Over 28 days the mean gastroparesis symptoms score continually improved more for the 0.5 mg PCS12852 group than the placebo group suggesting that longer treatment than 28 days may result in greater differences in gastroparesis symptoms for a 0.5 mg daily dose of PCS12852 than for placebo.
- The results, in addition to the previously announced improvements in gastric emptying in patients that received the daily dose of 0.5 mg of PCS12852, further support initiating a PCS12852 Phase 2B trial in 2023 for the treatment of gastroparesis.

HANOVER, MD, Dec. 14, 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, today announced positive top-line results on the clinical symptoms associated with gastroparesis from a 4-week Phase 2A study of PCS12852, which is being developed for the treatment of patients with gastroparesis. The trial was a placebo-controlled, randomized, dose-response study designed to evaluate the safety, efficacy, and pharmacokinetics of two dosage regimens of PCS12852 vs placebo (clinicaltrials.gov identifier NCT05270460). Processa previously announced an improvement in the primary endpoint of the study, the gastric emptying rate, in patients that received a 0.5 mg daily dose of PCS12852. The results from this Phase 2A study also showed that clinically meaningful improvements in gastroparesis symptoms occurred in more patients (i.e., a greater percentage of patients) receiving the PCS12852 0.5 mg daily dose than the placebo daily dose.

The study included 25 patients with moderate to severe gastroparesis that received a daily dose of PCS12852 (0.1 mg or 0.5 mg) or a placebo. Three patients dropped out of the study. Two patients were in the 0.5 mg group (one because of mild-moderate AEs and one did not provide a reason) and one in the 0.1 mg group (the reason was not provided by the patient). Gastroparesis symptoms were assessed using the American Neurogastroenterology and Motility Society Gastroparesis Cardinal Symptom Index Daily Diary (ANMS GCSI-DD), which is a validated patient-reported outcome instrument that

captures the daily core symptoms of gastroparesis. Publications have stated that a reduction from the baseline of greater than 0.5 in the total ANMS GCSI-DD score is clinically significant (Revicki 2012; Parkman 2018). The total GCSI score is the total of 5 symptom subscores which include nausea, vomiting, early satiety, postprandial fullness, and upper abdominal pain.

Although the study was not powered to show a statistically significant difference from the placebo, 100% of the patients receiving the 0.5 mg daily dose of PCS12852 and no rescue medication from Day 22-28 had a clinically meaningful reduction in the total ANMS GCSI-DD score (i.e., a reduction of greater than 0.5 from baseline) while only 57% of the placebo group had a clinically meaningful reduction. In addition, the magnitude of the improvement for the total ANNMS GCSI-DD score and for the subscores was greater for the 0.5 mg PCS12852 group than the placebo group. The 0.1 mg PCS12852 daily dose group showed little to no improvement in gastroparesis symptoms.

“This Phase 2A gastroparesis study shows a trend toward an increase in the gastric emptying rate and clinically meaningful improvements in gastroparesis symptoms in patients receiving a 0.5 mg daily dose of PCS12852,” said Dr. Sian Bigora, Chief Development Officer at Processa. “The reduction in clinical symptoms and the continued improvement in the total ANMS GCSI-DD score and multiple individual symptom scores were better for the PCS12852 0.5 mg daily dose group than placebo or the 0.1 mg group. These findings suggest that a longer treatment than 28 days may result in greater differences in the gastroparesis symptoms for the 0.5 mg PCS12852 daily dose group when compared to the placebo dose group. These results, consistent with the previous pre-clinical and clinical studies, give us confidence that dosing 0.5 mg of PCS12852 daily for at least 12 weeks should improve the clinical symptom score more than a placebo treatment.”

PCS12852 was shown to be generally well-tolerated, with most AEs occurring in the 0.5 mg dose group and consisting of either a mild or moderate grade. There were no clinically significant cardiovascular, unexpected, severe, or serious adverse events reported during the study.

With these positive results from the Phase 2A trial, Processa will be designing the Phase 2B trial and submitting it to their IND. Depending on priorities, funding, and licensing/partnering opportunities a Phase 2B trial could be initiated in 2023.

About PCS12852

PCS12852 is a novel, more potent, and more selective 5-hydroxytryptamine-4 (5-HT4) receptor agonist than other 5-HT4 agonists approved by FDA. Other 5-HT4 receptor agonists have been successful in treating GI motility disorders but given their affinity for other receptors, more off-target side effects such as cardiovascular side effects have occurred. In contrast, PCS12852 has been shown in non-clinical studies to be more potent and more selective than other 5-HT4 agonists resulting in fewer adverse events at the therapeutic range of treatment in pre-clinical studies and no reported serious adverse events in clinical studies. Other currently approved options for the treatment of gastroparesis have black box warnings and/or are limited due to adverse events.

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 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 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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