August 4, 2021

Processa Pharmaceuticals

Processa Announces First Patient Dosed in PCS6422 Study in Gastrointestinal Cancer

Processa's Phase 1b open label, multicenter trial is currently enrolling patients who have advanced, relapsed GI cancer that are refractory or intolerant to other therapies and are candidates for fluoropyrimidine monotherapy.

HANOVER, MD., Aug. 04, 2021 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (NASDAQ: PCSA), a clinical-stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have an unmet medical need condition, announced today it has dosed the first patient in its Phase 1b Dose-escalation Study of the Safety and Pharmacokinetics of Fixed-dose PCS6422 With Escalating Doses of Capecitabine Administered Orally to Patients With Advanced, Refractory Gastrointestinal Tract Tumors. Detailed information on the trial can be located at https://clinicaltrials.gov/ct2/show/NCT04861987

"We believe that the irreversible inhibitor effects of PCS6422 on the dihydropyrimidine dehydrogenase enzyme may significantly improve exposure to the cancer killing 5-FU metabolites while reducing the 5-FU metabolites, like α-fluoro-β-alanine, related to dose limiting side effects such as hand foot syndrome. The dosing of the first patient in our Phase 1b trial represents an important step to explore PCS6422's potential as a disease modifying therapy for capecitabine," said Dr. Sian Bigora, Chief Development Officer. "By the end of 2021, we expect to have interim results evaluating the positive effect that PCS6422 has on capecitabine while in 2022 we anticipate being able to define a new maximum tolerated dose and potential biomarkers for the PCS6422 - capecitabine combination which will help us to define the pivotal Phase 3 study design needed for FDA approval."

Dr. David Young, Chief Executive Officer, added, "The Processa strategy is to design and develop our pipeline of drugs to improve a patient's benefit-risk profile compared to existing therapy. PCS6422 is a prime example of the drugs in our pipeline and being able to enroll our first patient into this study is the first of many steps that we expect to achieve over the next 6-18 months."

The present site Principal Investigators are Dr. Jean Grem, Dr. Patrick Boland, Dr. Olivier Rixe, Dr. Sanjay Goel and Dr. Alexander Spira. The first patient was dosed by Dr. Olivier Rixe at Quantum Santa Fe.

About Processa Pharmaceuticals, Inc.

Our mission is to develop drug products that improve the survival and/or quality of life for patients with high unmet medical need conditions. We are a development company, not a discovery company, that seeks to identify and develop drugs for patients who need better treatment options than presently exist for their medical condition. To increase the probability

of development success, our pipeline only includes drugs which have previously demonstrated some efficacy in the targeted population or a drug with very similar pharmacological properties has been shown to be effective in the population.

We currently have three drugs in various stages of clinical development: PCS499 for Ulcerative Necrobiosis in Phase 2B; PCS3117 for metastatic pancreatic cancer and non-small cell lung cancer in Phase 2B; and PCS6422 for metastatic colorectal cancer and breast cancer in Phase 1B. The PCS12852 IND for the treatment of gastroparesis will be submitted in 3Q2021.

Members of the Processa development team throughout their careers have been involved with more than 30 FDA drug approvals (including drug products targeted to orphan disease conditions), more than 100 FDA meetings, and two FDA regulatory science contracts. 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 registration statement relating to the securities being sold in this offering, which identifies 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

James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

Processa Pharmaceuticals

Source: Processa Pharmaceuticals, Inc.