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Processa Pharmaceuticals

Processa Pharmaceuticals Doses First Patient in Amended Phase 1B Protocol for PCS6422 Combined with Capecitabine (Next Generation Capecitabine)

Processa focuses on identifying the PCS6422 regimens to increase capecitabine potency while identifying the MTD of Next Generation Capecitabine

The amended protocol will provide a more precise timeline of DPD inhibition and de novo formation while also supplying preliminary data on the use of an individualized-personalized medicine approach for Next Generation Capecitabine

HANOVER, MD, April 20, 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 unmet medical need conditions, announces today that the first patient with advanced, refractory gastrointestinal cancer has been dosed in its amended maximum tolerated dose (MTD) Phase 1B trial for Next Generation Capecitabine (the combination of PCS6422 and capecitabine) (NCT04861987).

The Company previously reported that a single dose of PSC6422 in this Phase 1B trial successfully inhibited dihydropyrimidine dehydrogenase (DPD), resulting in capecitabine approximately 50 times more potent (per mg of capecitabine administered) than FDA approved capecitabine, but the improved potency did not last throughout the seven days of capecitabine dosing.

Dr. David Young, Chairman and CEO of Processa said, "Our goal with Next Generation Capecitabine is to provide a more effective and/or safer therapy for patients with gastrointestinal cancer and other types of cancer. The revisions to the original protocol will now provide the data which will not only allow us to significantly increase the potency of Next Generation Capecitabine throughout capecitabine dosing but could also lead to more optimal dosing for each patient through an individualized-personalized medicine approach. We expect to have preliminary data on a better Next Generation Capecitabine regimen by mid-2022 and anticipate that the MTD for Next Generation Capecitabine will be determined by the end of 2022. We then plan to move to either a Phase 2B or Phase 3 trial in 2023 based on our discussions with FDA."

Next Generation Capecitabine (PCS6422 and Capecitabine)

Capecitabine is one of the most widely used chemotherapy agents in oncology and addresses a multi-billion-dollar market. It is an oral prodrug of 5-FU that converts to 5-FU. The problem with the current use of capecitabine is that approximately 80% of 5-FU is metabolized through catabolism to non-cancer killing metabolites that may cause dose-

limiting side effects such as hand-foot syndrome and cardiotoxicity while only 20% of 5-FU is metabolized through successive phosphorylation steps to active nucleotides which kill cancer cells. Given the catabolism is initialized through the DPD enzyme, PCS6422 (an irreversible inhibitor of DPD) decreases the catabolism of 5-FU resulting in more of the 5-FU being metabolized to active 5-FU nucleotides which may lead to an increase in the cell death potency for each mg of capecitabine administered. Thus, combining capecitabine with PCS6422 results in lower amounts of capecitabine needed to cause cell death, making the PCS6422-capecitabine combination a more potent and potentially safer Next Generation Capecitabine.

The Next Generation Capecitabine (PCS6422 administered with capecitabine) Phase 1B trial (NCT04861987) is a multi-center, maximum tolerated dose trial in patients with advanced, refractory gastrointestinal cancer. The amended Phase 1B trial is designed to evaluate the change in the metabolism of 5-FU when DPD has been inhibited, elucidate de novo formation of DPD in the presence of 5FU, and given the increased potency of capecitabine, the MTD of Next Generation Capecitabine. The metabolism and pharmacokinetics of capecitabine, 5-FU, and their metabolites are being evaluated as well as the dose-limiting toxicities and adverse event profile. Preliminary evidence of efficacy and further confirmation of the safety of Next Generation Capecitabine will also be obtained when possible.

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 (gastroparesis). The members of the Processa development team have been involved with more than thirty 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 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
301-651-4256
mfloyd@processapharmaceuticals.com

Patrick Lin
925-683-3218
plin@processapharmaceuticals.com

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