August 27, 2020

Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS ENTERED INTO A CONTINGENT PRECEDENT IN-LICENSING AGREEMENT WITH ELION ONCOLOGY FOR THE DEVELOPMENT OF ENILURACIL (PCS6422) FOR THE TREATMENT OF ADVANCED GASTROINTESTINAL TUMORS

HANOVER, MD, Aug. 27, 2020 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (OTCQB: PCSA) announced today that it has entered into a contingent precedent exclusive licensing agreement with Elion Oncology, Inc. to develop, manufacture and commercialize eniluracil (PCS6422) globally. PCS6422 is an oral drug to be administered with fluoropyrimidine cancer drugs (e.g., capecitabine, 5-FU) to decrease the breakdown of the cancer drug to inactive metabolites or metabolites that are known to cause unwanted side effects and to interfere with the anticancer activity.

Fluoropyrimidines are still the cornerstone of treatment for many different types of cancers, either as monotherapy or in combination with other chemotherapy agents. Capecitabine, an oral prodrug of 5-FU, is approved as first-line therapy for metastatic colorectal and breast cancer. However, its use is limited by adverse effects that usually requires dose interruptions/adjustments and even therapy discontinuation resulting in suboptimal tumor effects.

PCS6422 is an oral, potent, selective, and irreversible inhibitor of dihydropyrimidine dehydrogenase (DPD), the enzyme that rapidly metabolizes 5-FU to inactive metabolites, such as α-fluoro-β-alanine (F-Bal). F-Bal is thought to cause the neurotoxicity and Hand–Foot Syndrome associated with 5-FU while greater formation of F-Bal has been associated with a decrease in the antitumor activity of 5-FU. Inhibition of DPD by PCS6422 is expected to significantly increase the cancer exposure to the 5-FU cytotoxic metabolites, potentially improving tumor response while reducing side effects.

An IND for a Phase 1B study was cleared by the FDA in May 2020 and Processa plans to initiate the study in the first half of 2021. The study will evaluate the safety and tolerability of several dose combinations of PCS6422 and capecitabine in advanced gastrointestinal (GI) tumor patients.

“Having worked on 5-FU and other cancer agents in the past, adding PCS6422 to our pipeline and expanding our involvement in oncology was an easy decision given the

significant impact that PCS6422 may have on improving the efficacy and safety of capecitabine or other fluoropyrimidines," said Dr. David Young, CEO of Processa.

The grant of license is conditioned on the closing of an equity offering by Processa with at least $15 million in gross proceeds and the successful up-listing to Nasdaq by October 30, 2020. Following the satisfaction of the conditions, Processa must pay Elion $100,000 and issue Elion shares of common stock. As additional consideration, Processa will pay Elion development, regulatory, and commercial milestone payments up to a maximum of $88 million in cash and additional shares of common stock. Royalties on net sales will also be paid to Elion.

Additional information and updates are available on the company's website:
http://www.processapharma.com

About Processa Pharmaceuticals, Inc.

The mission of Processa has been to develop products where existing clinical evidence of efficacy already exists in unmet medical need conditions, medical conditions where patients need treatment options that will improve survival and/or quality of life. The Company has assembled a proven regulatory science development team, management team, and Board of Directors. The Processa development team has been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and 100 FDA meetings. For more information, please visit http://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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For More Information:
Patrick Lin
plin@processapharma.com
925-683-3218

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Source: Processa Pharmaceuticals, Inc.