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Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS ANNOUNCES FIRST PATIENT DOSED IN CLINICAL TRIAL TO EVALUATE THE SAFETY AND TOLERABILITY OF PCS-499 FOR THE TREATMENT OF NECROBIOSIS LIPOIDICA

HANOVER, MD, Jan. 29, 2019 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (OTCQB: PCSA), a clinical stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have high unmet medical need conditions, announced today the dosing of the first patient in the Phase 2 Necrobiosis Lipoidica (NL) clinical trial for PCS-499—which is taking place at 2 sites: University of Pennsylvania and University of Pittsburgh Medical Center (UPMC). Although the main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL, the safety and efficacy data collected from this study is expected to provide information for the design of future larger clinical trials.

Misha Rosenbach, M.D. is the Principal Investigator and an Associate Professor of Dermatology in the Perelman School of Medicine at the University of Pennsylvania. Dr. Rosenbach stated “Necrobiosis Lipoidica is an incredibly rare and often devastating disease for patients, and there is a need for high quality, evidence-based medicine to help guide therapeutic decision making. This has the potential to give us a new option to help our patients.”

The first subject was dosed at UPMC under the direction of Laura Ferris. M.D., Ph.D. Dr. Ferris is one of the Investigators for this study.

NL is a chronic, disfiguring condition affecting the skin and the tissue under the skin typically on the lower extremities with no currently approved FDA treatments. NL presents more commonly in women than in men and ulceration can occur in approximately 30% of NL patients. More severe complications can occur, such as deep tissue infections and osteonecrosis threatening life of the limb. Approximately 74,000 - 185,000 people in the United States and 200,000 – 500,000 people worldwide are affected by NL.

The degeneration of tissue occurring at the NL lesion site is caused by a number of pathophysiological changes which has made it extremely difficult to develop effective treatments for this condition. PCS-499 may provide a solution since PCS-499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

“We are excited to have our first NL patient dosed in this study. This is an important step in

demonstrating that PCS-499 may be a life-changing treatment for patients with NL" said David Young, Pharm.D., Ph.D., Processa's Chief Executive Officer. "We look forward to completing patient enrollment and providing top-line data later this year."

Additional information about our Phase 2 trial in NL patients can be found at https://clinicaltrials.gov/ct2/show/NCT03698864.

Editor's Note: *Rosenbach has consulted for Processa Pharmaceuticals and has received honoraria.*

About Processa Pharmaceuticals, Inc.

Processa Pharmaceuticals, Inc. was founded in 2017 in Hanover, Maryland, with a mission to develop products that can improve the survival and/or quality of life for patients who have a high unmet medical need. The Company acquired the assets of Promet Therapeutics, LLC in October of 2017 and assembled a proven regulatory science development team, management team, and Board of Directors. The Processa drug development team members have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and 100 FDA meetings. PCS-499 represents the first Processa drug that can potentially be used in a number of unmet medical need conditions. 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 that could cause actual results to differ from those contained in the forward-looking statements.

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