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Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS TO MOVE FORWARD WITH A PCS499 PHASE 3 TRIAL AFTER A SUCCESSFUL FDA MEETING

HANOVER, MD, March 30, 2020 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (OTCQB: PCSA), announced the successful completion of their meeting with the U.S. Food and Drug Administration (FDA) for PCS499, its investigational product targeting the treatment of Necrobiosis Lipoidica (NL).

During the meeting Processa and the FDA discussed the clinical program as well as the nonclinical and clinical pharmacology plans to support the submission of the PCS499 New Drug Application (NDA) in the U.S. for the treatment of ulcers in NL patients. With input from the FDA through a Special Protocol Assessment, Processa will be designing and conducting a Phase 3 trial to evaluate the ability of PCS499 to completely close ulcers in patients with NL. Processa initially planned to begin recruiting for this trial in Q4 2020 but with the COVID-19 pandemic, it is expected that this trial will begin recruiting patients in 2021. FDA will determine if a second confirmatory Phase 3 trial is required after reviewing the results from this first trial.

"We are pleased with the outcome of the FDA meeting and the feedback we received from the FDA. We believe that the results from our completed Phase 2 trial in NL patients, especially those with more severe ulcerated forms of NL, are encouraging and we appreciate the guidance provided by the FDA regarding our next clinical trial and the requirements to support our NDA submission. We look forward to working with the FDA in designing a Phase 3 trial that will demonstrate the efficacy and safety of PCS499 for a NDA approval,'" said Dr. David Young, Chief Executive Officer at Processa.

NL is a chronic, disfiguring condition affecting the skin and tissue under the skin typically on the lower extremities with no currently approved FDA treatments. 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 more than 200,000 – 500,000 people outside the United States are affected by NL with the prevalence of open ulcers being approximately 30% of all NL patients. 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. At this time there is no approved FDA treatment for NL and PCS499 could be the first drug approved. PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with NL.

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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