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Processa Pharmaceuticals

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

HANOVER, MD, Aug. 26, 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 last patient has been enrolled in the Phase 2 Necrobiosis Lipoidica (NL) clinical trial for PCS-499.

Completing the enrollment of the last patient in this clinical trial represents a significant clinical development milestone for PCS-499 and moves us a step closer to potentially bringing this new treatment forward to help patients suffering from NL.

“We are pleased to have completed patient enrollment ahead of schedule. These patients suffer from this chronic, disfiguring condition with lesions and ulcerations and there is currently no treatment available. We look forward to having top-line data on safety and efficacy later this year and then meeting with the FDA as we determine next steps in moving the product through to approval.” said Dr. Sian Bigora, Chief Development Officer.

“We are very pleased to have accomplished this clinical milestone and would like to thank the patients, their families, and the clinical sites who are participating in the study.” said Dr. David Young, Chief Executive Officer.

As previously announced in a July 15 press release, the PCS-499 dose of 1.8 grams/day, 50% greater than the maximum tolerated dose of pentoxifylline, appears to be well tolerated with no serious adverse events reported. In addition, we have seen very positive efficacy trends in the patients enrolled in this clinical trial.

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 over 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.

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

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 has 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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