PROCESSA PHARMACEUTICALS PROVIDES A STUDY UPDATE FOR ITS ON-GOING PHASE 2 SAFETY AND TOLERABILITY CLINICAL TRIAL OF PCS-499

HANOVER, MD – July 15, 2019 – 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 a high unmet medical need condition, provides an update for its on-going Phase 2 Necrobiosis Lipoidica (NL) clinical trial for PCS-499 (PCS499-NL01), a deuterated analog of one of the major metabolites of pentoxifylline (Trental®).

Our Phase 2 trial is approaching six months from the announcement of the first patient dosed. Although the main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL, safety and efficacy data collected from this trial is expected to provide information for the design of future clinical trials. Based on toxicology studies and healthy human volunteer studies, Processa and the FDA agreed that a PCS-499 dose of 1.8 grams/day would be the highest dose administered to NL patients in this Phase 2 trial. As anticipated, 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. Currently ten patients have been dosed with seven patients being on treatment for at least 3 months and three patients on treatment for 5 months. To date, six of the ten patients dosed at 1.8 g/day have reported only mild adverse events related to the treatment, which occurred mostly in the first month of treatment and were quickly resolved. As expected, gastrointestinal or CNS adverse events were reported most often.

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 more than 200,000 – 500,000 people outside the United States 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 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. PCS-499 represents the first Processa drug that can potentially be used in several 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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