Processa Announces Sites Selected for Phase 2B Clinical Trial to Treat Patients with Ulcerated Necrobiosis Lipoidica

HANOVER - March 17, 2021 - Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient's survival and/or quality of life, today announces that it has selected 5 U.S. clinical sites to enroll patients with ulcerative necrobiosis lipoidica for the Company's Phase 2B trial "A Randomized, Double-blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of PCS499 in Treating Ulcerations in Patients who Have Necrobiosis Lipoidica." Two to three additional clinical sites will be selected in the future including sites outside the U.S.

Dr. Misha Rosenbach, Department of Dermatology at the University of Pennsylvania, is the Principal Investigator on the study. A summary of the study and a listing of the sites selected can be found at https://clinicaltrials.gov using the NCT number of NCT04800562. The study is expected to begin recruiting patients within the next 30-60 days.

Necrobiosis Lipoidica (NL) is a rare, painful condition affecting the skin and tissue under the skin typically on the lower extremities. Ulcerations occur in up to 35% of patients with NL, many times following minor trauma. Ulcerations often prove challenging to treat and may lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten the life of the limb and lead to amputation. The ulcers run a refractory course and usually are resistant to treatment. The ulcers in NL can be painful leading to impaired quality of life for these patients. The pathogenesis of NL remains unclear and although various drugs have been tried, none of them is consistently effective. PCS499 and its metabolites affect a number of biological pathways, several of which contribute to the pathophysiology associated with ulcerative NL.

"We have selected 5 US sites to evaluate this ground-breaking new treatment for ulcerative necrobiosis lipoidica and we expect to add a few more sites in the next few months including sites outside the U.S. Unfortunately for patients with ulcerative necrobiosis lipoidica, open ulcers often take years to naturally heal, if they heal at all, and treatments to close the ulcers in these patients do not exist. Fortunately, our preliminary clinical evaluation of PCS499 in the treatment of patients with ulcerative necrobiosis lipoidica suggests that PCS499 may be effective in closing these ulcers within months of starting treatment," said Dr. Sian Bigora, Chief Development Officer at Processa.

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (GI motility/gastroparesis). The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's website at **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 registration statement relating to the securities being sold in this offering, which identifies important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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