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# Processa Pharmaceuticals Announces Launch of Website to Increase Awareness of Ulcerative Necrobiosis Lipoidica and to Inform Patients of the ongoing Phase 2B Study of PCS499

HANOVER, MD, Aug. 04, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (NASDAQ: PCSA), ("Processa" or the "Company"), a clinical-stage biopharmaceutical company developing products to improve the survival and/or quality of life for patients who have unmet medical need conditions, announces today that it has launched a new website Necrobiosislipoidicastudy.com. The website is designed to increase awareness of ulcerative Necrobiosis Lipoidica ("uNL"), an extremely rare condition, and to inform patients about the ongoing Phase 2 study that is investigating the use of PCS499 for the treatment of this rare condition.

Necrobiosis Lipoidica (NL) is a chronic skin condition with no currently approved U.S. Food and Drug Administration (FDA) treatment. It is believed that NL affects 22,000 – 50,000 people in the United States and is more common in individuals with diabetes and women, with an average age of onset between 20 and 60 years. People with NL experience a persistent skin condition that develops into ulcerated lesions in about one-third of cases. Ulceration can cause severe complications, such as life-threatening infections and necrosis.

Processa Pharmaceuticals is conducting a randomized, double blind, placebo-controlled study that will evaluate the efficacy and safety of PCS499 as compared to placebo for the treatment of ulcerations of patients with Necrobiosis Lipoidica (NCT#NCT04800562). This study is currently recruiting in the United States and is expected to enroll a total of 20 patients.

Sian Bigora, Pharm.D., Chief Development Officer, said, "For patients with NL, the tissue below the skin can become necrotic forming open ulcers which can last from months to years with complications such as infections, amputation, and cancer. Currently there is no FDA approved treatment for uNL or NL, no standard of care, and the treatments that are used are generally inadequate. We are conducting the Phase 2b study to hopefully show that PCS499 can be an option for these patients who currently have little to no options available"

For more information on the clinical study of PCS499, please visit Necrobiosislipoidicastudy.com

**PCS499**

PCS499, is a deuterated analog of a major metabolite of pentoxifylline (PTX or Trental®).

PCS499 and its active metabolites have a diverse pharmacology profile and can act on multiple targets that play vital roles in the treatment of various conditions. Investigators postulate that PCS499 may provide a novel treatment solution for NL thanks to its metabolites, which affect many of the biological pathways that contribute to the physiological processes associated with NL.

**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 (gastroparesis). The members of the Processa development team have been involved with more than thirty 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 that 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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