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PROCESSA PHARMACEUTICALS ANNOUNCES RESULTS FROM THE PHASE 2 STUDY IN NECROBIOSIS LIPOIDICA

HANOVER, MD, March 17, 2020 (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 a high unmet medical need condition, announced the completion of its Phase 2 Necrobiosis Lipoidica (NL) clinical trial for PCS-499 (PCS499-NL01), a deuterated analog of one of the major metabolites of pentoxifylline (Trental®).

The Phase 2 trial was a multicenter, open-label prospective study designed to determine the safety and tolerability of PCS-499 in patients with NL. The last patient completed the study in February 2020. The fully enrolled trial included twelve NL patients: two patients with open ulcers and ten patients with the mild to moderate form of NL and no ulcerations.

PCS-499 was found to be safe and well tolerated in these patients at doses of 1.8 grams/day with no serious adverse events reported. Adverse events assessed as possibly/probably related to PCS-499 were reported by seven patients and were reported as mild and occurred mostly in the first few weeks of treatment and quickly resolved. As expected, gastrointestinal adverse events were reported most often.

The two patients presenting with more severe ulcerated NL had ulcers for more than two months prior to dosing. At baseline the reference ulcer in one of the two patients measured 3.5 cm² and had completely closed by Month 2 of treatment. The second patient had a baseline reference ulcer of 1.2 cm² which completely closed by Month 9. In addition, while in the trial one of these patients also developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month. The other ten patients presenting with mild to moderate NL and no ulceration had some improvement of the NL lesions but not as dramatic as the more serious ulcerated patients.

“We are pleased to successfully complete this Phase 2 trial and are encouraged by the positive safety and efficacy results obtained from the trial. On PCS-499 all the ulcers on our two ulcerated patients were completely closed, something that we believe occurs naturally in less than 10% of the patients with ulcers. PCS-499 may offer a new treatment for this chronic disfiguring condition and we are meeting with the FDA later this month to define the Phase 3 trial for NL patients with ulcers,” said Dr. Sian Bigora, Chief Development 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. 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.

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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