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Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS PROVIDES AN UPDATE ON POSITIVE RESULTS FROM PCS-499 PHASE 2 TRIAL

HANOVER, MD, Dec. 04, 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 a high unmet medical need condition, provides an update on 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®).

The main objective of the trial is to evaluate the safety and tolerability of PCS-499 in patients with NL. 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. The trial is fully enrolled at twelve patients with eight of these patients completing six months of treatment and seven continuing into an extension period.

Our findings to date are:

- 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. Adverse events have been mild, as previously reported, occurring mostly in the first few weeks of treatment and quickly resolved. As expected, gastrointestinal adverse events were reported most often and no patients have discontinued because of an adverse event.
- From our preliminary efficacy data, two patients presented with more severe ulcerated NL. Both ulcerated patients had ulcers for more than two months prior to dosing. In both patients, the ulcers fully closed at two and nine months, respectively. In addition, while in the trial one of the ulcerated patients also developed small ulcers at other sites as a result of contact trauma to the site and these ulcers resolved within one month.
- Ten patients presented with mild to moderate NL and no ulceration. These patients have shown a slight improvement but not as dramatic as the more serious ulcerated patients.

“Based on the literature and clinical experience, approximately 30% of the patients with NL are expected to have open ulcers with the ulceration naturally healing in only 20% of these patients. Our positive preliminary efficacy in the two ulcerated patients is a small sample size but is very encouraging given closure of ulcers normally occurs in so few patients. Based on the efficacy and safety we plan to meet with the FDA to further discuss the PCS-499 development plan including an adaptively designed pivotal clinical trial for the treatment of patients with NL ulcers” said Dr. David Young, Chief Executive Officer.

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. 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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