July 12, 2022

Processa Pharmaceuticals to Present at the World Orphan Drug Congress USA, July 11-13, 2022

HANOVER, MD., July 12, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage biopharmaceutical company developing drugs to improve the survival and/or quality of life for patients who have unmet medical conditions announced today that Dr. David Young, it's Chief Executive Officer, will present "Thinking Regulatory First - Considerations for the Effective Development of Rare Disease Therapies" at the World Orphan Drug Congress USA 2022 Conference on Wednesday, July 13, 2022 at 3:25 pm EDT.

"The Processa team has successfully developed a number of drugs over the last 30 years with over 30 FDA approvals, some in Orphan indications." Said Dr. David Young, CEO. "For example, while at Questcor, this team was able to successfully obtain the FDA approval for an Acthar supplemental New Drug Application for the treatment of infantile spasms, an ultra-rare orphan condition. Through our collaboration with the FDA, we were able to define the clinical studies and regulatory path required to demonstrate that the benefits of Acthar for the treatment of infantile spasms outweighed the risks associated with Acthar treatment, the risks of using Acthar off-label with various regimens, and the risks associated with the natural progression of infantile spasms without Acthar treatment."

Although Processa has a pipeline of 5 drugs, 3 of which have FDA Orphan Designation, we are only developing 2 for the treatment of an orphan indication. PCS499 is being developed for the treatment of the serious orphan indication, ulcerative Necrobiosis Lipoidica ("uNL"), and PCS3117 is being developed for the treatment of pancreatic cancer.

PCS499 is currently in Phase 2B trial given that some efficacy has already been demonstrated in a proof-of-concept Phase 2A trial. The enrollment of the interim analysis cohort within the Phase 2B trial should be completed over the next few months with the analysis of this interim cohort of patients occurring in the 1H of 2023. The study is expected to complete enrollment by the end of 2022. Currently, there are no FDA approved drugs for uNL or NL and the drugs used off-label do not provide adequate treatment benefits while having adverse events profiles that minimize their use.

PCS3117 has an IND in pancreatic cancer and Phase 2A data demonstrating efficacy in various targeted pancreatic cancer patients (e.g., treatment naïve patients and patients who are refractory to existing therapy). Processa is presently designing the potential development programs and will determine which has the greatest chance of FDA approval after meeting with the FDA at the end of 2022. Positioning PCS3117 as 1st, 2nd or 3rd line therapy will not only be important for approval but also for commercialization.

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 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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Source: Processa Pharmaceuticals, Inc.