June 22, 2018

Processa Pharmaceuticals Receives Orphan Designation Status For PCS499 In Necrobiosis Lipoidica From The Food And Drug Administration (FDA)

HANOVER, Md., June 22, 2018 /PRNewswire/ -- Processa Pharmaceuticals, Inc. (OTC: 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, announced today that the U.S. Food and Drug Administration (FDA) has granted orphan-drug designation to its leading clinical compound PCS499 for treatment of Necrobiosis Lipoidica (NL).

"We are very pleased that PCS499 has received Orphan Drug Designation from FDA for the treatment of NL. NL can have a major impact on the quality of life of patients and PCS499 will be the first treatment targeted to this condition. We plan to begin our clinical studies in 2018 and to accelerate the development of PCS499 in order to provide clinical benefit to NL patients as soon as possible," said Dr. David Young, CEO Processa Pharmaceuticals, Inc.

Approximately 74,000 - 185,000 people in the United States and 200,000 – 500,000 people worldwide are affected by NL. These numbers include non-diabetic patients and 0.3% of all diabetic patients. NL is a multi-faceted disorder affecting the skin and the tissue under the skin and occurs in women/men 20 – 60 years of age with the potential to last for months or years. There is currently no FDA approved treatment and no known biotech or pharma companies developing a drug for NL.

The FDA Office of Orphan Products Development grants Orphan Drug Designation to investigational drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including seven years of market exclusivity upon regulatory product approval, exemptions from certain FDA application fees, and tax credits for qualified clinical trials costs.

Forward-looking statements 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.

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 acquired the assets of Promet Therapeutics, LLC in October of 2017 and has assembled a proven regulatory science product development team, management team, and Board of Directors. The Processa Team's expertise is in developing drug products from IND enabling studies to NDA submission. The Company's combined scientific, development and regulatory experience has resulted in 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

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