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Processa Pharmaceuticals

# PROCESSA PHARMACEUTICALS ANNOUNCES THE LICENSING OF AN ANTI-FIBROTIC, ANTI-INFLAMMATORY DRUG FOR THE TREATMENT OF MULTIPLE UNMET MEDICAL NEED CONDITIONS

HANOVER, MD, Sept. 03, 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, announced today that they have signed an exclusive worldwide license agreement with Akashi Therapeutics to develop and commercialization Akashi's lead drug, HT-100.

HT-100 is an orally available anti-fibrotic, anti-inflammatory drug that also promotes healthy muscle fiber regeneration. In previous clinical trials in Duchenne Muscular Dystrophy (DMD), HT-100 showed promising improvement in the muscle strength of non-ambulant pediatric patients. Although FDA placed a clinical hold on the DMD trial after a serious adverse event in a pediatric patient, FDA has removed the drug off of clinical hold and defined how HT can resume clinical trials in DMD.

Processa plans to begin developing HT-100 in rare adult fibrotic related diseases such as focal segmental glomerulosclerosis (FSGS), idiopathic pulmonary fibrosis (IPF) or Scleroderma, where there are still few therapeutic options. The company will revisit potential pediatric indications, such as DMD, at a later time.

"Processa needs to learn more about the safety and dose response of HT-100 while we determine the best way to clinically manage patients on this anti-fibrotic drug," said Dr. Sian Bigora, Chief Development Officer at Processa Pharmaceuticals. "In early 2020 we hope to begin to define, in collaboration with the FDA, an efficient way to develop HT-100 for all those patients who would benefit from this drug."

Dr. David Young, Chief Executive Officer at Processa, added, "The Processa strategy is to add drugs to our portfolio which already have some clinical evidence of efficacy. This enables our team to efficiently develop these drugs for patients with a high unmet medical need condition while the risk of failure associated with the clinical trials is decreased. This strategy was implemented when PCS-499 was acquired and will now be implemented for HT-100. Since the quality of life for these patients is so often impaired given the lack of treatment options, the more efficiently we can develop these products, the sooner patients will experience the positive impact of these drugs on their lives."

Additional information and updates are available on our website:

http://www.processapharma.com

**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 drug development team members have 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 that could cause actual results to differ from those contained in the forward-looking statements.

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Source: Processa Pharmaceuticals, Inc.