

March 21, 2018



# **Processa Pharmaceuticals Announces That It Has Been Assigned The License For The Clinical Stage Compound CTP-499 And Plans To Develop The Drug In Multiple Unmet Medical Need Conditions**

HANOVER, Md., March 21, 2018 /PRNewswire/ -- Processa Pharmaceuticals, Inc. (OTC: PCSA) announced today that, as agreed in the asset purchase of Promet Therapeutics, LLC, Processa has been assigned the license for CTP-499 upon Promet's exercising of the exclusive option to license in CTP-499 from Concert Pharmaceuticals, Inc.

CTP-499 is an analog of an active metabolite of an approved drug and has multiple pharmacological targets that can be used to its advantage. The compound has already been shown to be safe with a trend toward efficacy in diabetic nephropathy (DN).

Processa has identified other unmet medical need conditions. In these conditions, preliminary clinical evidence already exists demonstrating that affecting the multiple pharmacological targets of CTP-499 results in a positive clinical response in some patients. Processa has met with the FDA on the first indication, Necrosis Lipoidica (NL), a chronic, disfiguring condition for which most patients do not have any treatment options. NL develops more commonly in women than in men on the pretibial region of the lower extremities, usually presenting initially as red papules that enlarge to form patches or plaques with an atrophic yellow center. Ulceration occurs in approximately 30% of NL patients, which can lead to more severe complications, such as deep tissue infections and osteonecrosis that can threaten life of the limb.

"Our vision is to EFFICIENTLY develop drug products for patients who have high unmet medical need conditions. "EFFICIENTLY" because patients who have conditions that severely impair their quality of life with no treatment options, like NL patients, need drug products that will have a major positive impact on their lives as soon as possible. Based on the epidemiology literature on NL, there appears to be 75,000- 180,000 patients in the US and more than 200,000 – 500,000 patients worldwide with this condition and no adequate treatment." Dr. David Young, CEO of Processa, said. He added "the Processa development team has already met with the FDA on NL and has a solid strategy for moving forward with the development of CTP-499 in NL starting with a Phase 2 clinical trial in NL patients in 2018. We also hope to meet with the FDA on a second clinical stage indication for CTP-499 in the next few months. Although Concert obtained a positive trend in a Phase 2 study in DN, the primary endpoint and sample size required by FDA for a pivotal study makes this a more difficult indication for Processa to pursue at this time given the low probability of success of any drug in DN and the resource/time commitment for a pivotal DN study."

Concert has granted to Promet an exclusive license, including the right to assign the license,

sublicense, develop, manufacture, use and commercialize CTP-499 worldwide. Upon exercising the option to license CTP-499, Promet is transferring \$8 million of its Processa shares, approximately 5.9% of all Processa outstanding shares, to Concert with Concert also being eligible to receive royalties on commercial sales. Promet with Concert's agreement has subsequently assigned the license to Processa after exercising the licensing option.

Additional information and updates are available on the company's 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 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, 100 meetings with FDA and more than 50 drug development programs, including drug products targeted to orphan disease conditions. For more information, please visit <http://www.processapharma.com>

For More Information:

Investor Relations: Patrick Lin

[plin@processapharma.com](mailto:plin@processapharma.com)

925-683-3218

 View original content: <http://www.prnewswire.com/news-releases/processa-pharmaceuticals-announces-that-it-has-been-assigned-the-license-for-the-clinical-stage-compound-ctp-499-and-plans-to-develop-the-drug-in-multiple-unmet-medical-need-conditions-300617256.html>

SOURCE Processa Pharmaceuticals