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Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS ENTERS INTO A LICENSING AGREEMENT WITH YUHAN CORPORATION FOR THE DEVELOPMENT OF YH12852 IN FUNCTIONAL GASTROINTESTINAL DISORDERS

HANOVER, MD, Aug. 20, 2020 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (OTCQB: PCSA) announced today that it has entered into a licensing agreement with Yuhan Corporation, a South Korean based company, to license in YH12852. YH12852 is a small molecule drug in development for the treatment of functional gastrointestinal (GI) disorders (FGID).

Under the terms of the agreement, Processa will acquire the rights to a portfolio of patents with an exclusive license to develop, manufacture and commercialize YH12852 globally, excluding South Korea, where Yuhan will retain such rights. In exchange, Yuhan shall receive $2 million of Processa common stock in a non-refundable, non-creditable upfront payment. Yuhan is eligible to receive success-based development, regulatory and commercial milestone payments totaling a maximum of $408.5 million as well as royalties on net sales.

YH12852 is a novel, potent and highly selective 5-hydroxytryptamine 4 (5-HT4) receptor agonist. Other 5-HT receptor agonists with less 5-HT4 selectivity have been shown to successfully treat GI mobility disorders such as chronic constipation, constipation-predominant irritable bowel syndrome, functional dyspepsia and gastroparesis. The less selective 5-HT4 agonists, such as cisapride, have been either removed from the market or not approved because of the cardiovascular side effects associated with the drugs binding to other receptors, especially 5-HT receptors other than 5-HT4.

Yuhan had previously conducted extensive toxicological studies and Phase 1 studies for YH12852 which demonstrated that the product is safe for use and can be moved quickly into Phase 2 studies.

Processa intends to meet with the FDA in early 2021 to further define the clinical development program. In 2021, Processa expects to initiate a Phase 2 trial in a functional GI motility-related disorder that needs better therapeutic options, such as postoperative ileus and opioid-induced constipation.

“Sometimes it takes new strategies to find a way to maximize the value of new medicine. We are very pleased by this partnership with Processa who has the core expertise needed for the development of YH12852, and we look forward to working together to make this work,”

said Jung Hee Lee, Chief Executive Officer of Yuhan Corporation.

“The agreement with Yuhan is further evidence of Processa’s commitment to seek out novel treatments for unmet medical conditions,” commented Dr. David Young, CEO of Processa. “Everyone has had some type of GI problem in their life from acute episodes to more chronic problems. Processa’s plan is to demonstrate that YH12852 may provide a treatment for those patients who have the more serious, chronic or reoccurring GI motility problems. Functional GI motility-related symptoms can significantly alter a person’s life and our goal will be to demonstrate how YH12852 can provide a better option than what is presently available to these patients.”

Dr. Sian Bigora, Chief Development Officer at Processa said, “We believe that Processa’s strong scientific expertise in gastrointestinal disorders makes it well positioned to advance this product forward and maximize its potential for patients around the world.”

Additional information and updates are available on the company’s website: http://www.processapharma.com

About Processa Pharmaceuticals, Inc.

The mission of Processa has been to develop products where existing clinical evidence of efficacy already exists in unmet medical need conditions, medical conditions where patients need treatment options that will improve survival and/or quality of life. The Company has assembled a proven regulatory science development team, management team, and Board of Directors. The Processa development 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. For more information, please visit http://www.processapharma.com.

About Yuhan Corporation, Inc.

Yuhan Corporation is a South Korea-based healthcare company founded in 1926. The company has positioned itself as one of the top pharmaceutical companies in terms of market cap and sales revenue in Korea. The core business consists of primary & specialty care, dietary supplements, household & animal care, and contract manufacturing of active pharmaceutical ingredients. It has a number of subsidiaries and a global presence in the form of joint ventures with the Clorox Company (USA) and Kimberly-Clark Corporation (USA). Yuhan (000100:KS) is a publicly-listed company traded on the Korea Stock Exchange.

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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