June 1, 2020

Processa Pharmaceuticals

PROCESSA PHARMACEUTICALS ANNOUNCES THAT IT HAS ENTERED INTO AN AGREEMENT WITH APOSENSE, LTD TO LICENSE IN THE NEXT GENERATION IRINOTECAN DRUG

HANOVER, MD, June 01, 2020 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (OTCQB: PCSA) announced today that it has signed an agreement with Aposense, LTD. to license in the patent rights and the know-how to develop and commercialize their next generation irinotecan cancer drug, ATT-11T.

Irinotecan metabolizes to SN-38, the active anti-cancer moiety, and is used as first and second line therapy in many types of cancer (e.g., metastatic colorectal, small cell lung, pancreatic). Although irinotecan has a narrow therapeutic window and dose limiting adverse effects, including a FDA “Black Box” warning for both neutropenia and severe diarrhea, irinotecan achieved peak annual sales of US$1.1 billion.

ATT-11T is a novel lipophilic anti-cancer pro-drug that is being developed for the treatment of the same solid tumors as prescribed for irinotecan. This pro-drug is a conjugate of a specific proprietary Aposense molecule connected to SN-38, the active metabolite of irinotecan. The proprietary Aposense molecule on ATT-11T allows ATT-11T to bind to cell membranes to form an inactive pro-drug depot on the cell with SN-38 preferentially accumulating in the membrane of tumors cells and the tumor core. This unique characteristic is expected to make the therapeutic window of ATT-11T wider than irinotecan such that the anti-tumor effect of ATT-11T will occur at a much lower dose than irinotecan with a milder adverse effect profile than irinotecan. The wider therapeutic window will likely lead to more patients responding with less side effects when on ATT-11T compared to irinotecan.

“The licensing of this product from Aposense fits with our strategy to continue to bring innovative products to patients with an unmet medical need condition. With the addition of this product to our pipeline, the Processa team is excited about moving into the cancer arena,” said Dr. David Young, Chief Executive Officer of Processa.

The licensing agreement is a Condition Precedent License Agreement conditioned upon: (i) Processa’s closing of the Satisfactory Financing Round and the listing of the Company’s shares on the NASDAQ or NYSE and (ii) Aposense obtaining the approval of the Israel Innovation Authority for the consummation of the transactions set forth in the agreement. Subject to the terms of the Agreement and upon satisfaction of the conditions, Aposense will grant Processa a worldwide (excluding China), royalty-bearing right and license, including the right to sublicense. Under the terms of the License Agreement, Aposense will receive shares in Processa with an aggregate value of $2.5 M and could receive up to $125 M in potential development and sales milestones, as well as royalties of 7% based on net sales.

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

About Processa Pharmaceuticals, Inc.

The mission of Processa is 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.

About Aposense, LTD.

Aposense is a highly innovative Israeli bio-pharmaceutical company, specializing in development of novel drugs, utilizing membrane electrical forces. Among others, Aposense developed a universal platform technology entitled Molecular Nano-Motors (MNMs) for the delivery of genetic drugs, such as siRNA, into cells.

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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