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Processa Pharmaceuticals

Processa Pharmaceuticals Announces Positive Preclinical Data for NGC-Iri

Delivers more cancer-killing SN-38 molecules to tumor than irinotecan and Onivyde®

Studies support potential benefit as an improved treatment with fewer side effects

HANOVER, Md., Aug. 19, 2024 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) announces positive data from preclinical studies that support the potential for NGC-Iri to have improved efficacy and a better side effect profile compared with the commonly used FDA-approved cancer treatments irinotecan and Onivyde® (the liposomal formulation of irinotecan). Next Generation irinotecan (NGC-Iri) is a prodrug of SN-38, which is the active anticancer metabolite of irinotecan.

In two studies with the human melanoma xenograft mouse model, the accumulation of SN-38 in the tumor plasma and other tissues following treatment with NGC-Iri and Onivyde® were compared with the accumulation following treatment with irinotecan. One study compared NGC-Iri with irinotecan, and the other compared Onivyde® with irinotecan. The two studies demonstrated that in mice that were administered the same amount of SN-38:

- Accumulation of SN-38 in the tumor compared with other tissues, such as muscle, was greater after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the tumor-to-muscle ratio of approximately 200 for NGC-Iri and less than 15 for irinotecan and Onivyde®;
- More SN-38 accumulated in the tumor after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the tumor-to-plasma ratio being approximately 10 for NGC-Iri and less than 7 for irinotecan and Onivyde®; and
- Less SN-38 accumulated in non-cancer tissues, such as muscle, after NGC-Iri administration than after irinotecan or Onivyde® administration, as demonstrated by the muscle-to-plasma ratio being less than 0.10 for NGC-Iri and greater than 0.4 for irinotecan and Onivyde®, supporting the potential for a better NGC-Iri safety profile.

“Many patients are unable to complete their treatment regimen due to the significant side effects related to irinotecan and Onivyde®, both of which have black box warnings in their labels,” stated David Young, PharmD, Ph.D., President of Research and Development at Processa Pharmaceuticals. “Given the greater SN-38 exposure in tumors, and less exposure in tissue outside the tumors, we believe NGC-Iri may have a more favorable efficacy and side-effect profile, and therefore prove to be an improved alternative to irinotecan and Onivyde®.”

Processa is currently defining the regulatory path for NGC-Iri, which includes identifying the target patient population and the type of cancer to present to the FDA. Once defined, the Company will provide an update on the regulatory pathway and timeline.

Irinotecan is a chemotherapy utilized to treat a variety of solid tumors, including colorectal, pancreatic, ovarian and lung. It is used as first-line therapy, combined with other chemotherapy agents, for metastatic colon and rectal cancers and extensive stage 4 small cell lung cancer (SCLC). In addition, irinotecan is used as second- or third-line therapy for several other solid tumors (e.g., metastatic pancreatic, metastatic gastric, esophageal, breast, relapsed or refractory stage 4 SCLC). Despite the black box warning for severe side effects, in 2021 Medicare reported a total of more than 1.8 million doses of irinotecan and Onivyde®.

About NGC-Iri

NGC-Iri is a prodrug of SN-38, the active molecule in irinotecan and Onivyde®. NGC-Iri is designed to improve the pharmacokinetic (PK) profile and preferentially distribute SN-38 to cancer cells over normal cells. A molecule is attached to SN-38 that is preferentially attracted to the internal electric field of the cancer cell membrane over normal cells, resulting in intra-membrane prodrug depots of NGC-Iri.

Animal distribution and PK studies have shown that NGC-Iri not only preferentially distributes SN-38 to cancer cells over normal cells, but the half-life of SN-38 is significantly extended. In addition, SN-38 after NGC-Iri distributes more to cancer cells and less to other tissues compared with irinotecan and Onivyde®. Dose-ranging studies in the human melanoma xenograft mouse model have demonstrated that there is a wide range of doses that result in similar efficacy but show a difference in safety.

About Processa Pharmaceuticals, Inc.

Processa is a clinical-stage pharmaceutical company focused on developing the Next Generation Chemotherapy (NGC) drugs with improved safety and efficacy. Processa's NGC drugs are modifications of existing FDA-approved oncology therapies resulting in an alteration of the metabolism and/or distribution of these drugs while maintaining the existing mechanisms of killing the cancer cells. By combining its novel oncology pipeline with proven cancer-killing active molecules and its Regulatory Science Approach, Processa's strategy is to develop more effective therapy options with improved tolerability for cancer patients through an efficient regulatory path.

For more information, visit our website at 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 which could cause actual results to differ from those contained in the forward-looking statements.

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