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Processa Pharmaceuticals

Processa Pharmaceuticals CEO Dr. David Young Issues Letter to Shareholders Providing Outlook for 2022

HANOVER, MD., Jan. 26, 2022 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical stage company developing drugs for patients who have unmet medical conditions that require better treatment options to improve a patient's survival and/or quality of life, today released the following letter to shareholders from its Chief Executive Officer Dr. David Young.

Dear Fellow Shareholder:

As we start a new year, I want to thank you for your support and take this opportunity to share our accomplishments in 2021 and our planned path forward. We believe 2022 will be a transformative year for Processa as our multi-asset pipeline continues to mature and we achieve important clinical milestones.

Our pipeline is different from that of other biotech companies because each of our drugs have a "de-risked" development path forward which includes:

- targeting patients with unmet medical need conditions who either have no treatment option or require better options to improve their survival and/or quality of life;
- some clinical evidence of efficacy and safety in the targeted treatment population for the drug itself or a drug with similar pharmacological properties; and
- a more efficient Regulatory Science development path with greater probability of success.

Processa is a "drug development company" not a drug discovery company. Our pipeline of drugs does not include a new drug class or new drug target like many discovery companies. Our efforts and energies are directed toward advancing each program as efficiently as possible to the next development stage while obtaining information that will assist us in ultimately obtaining marketing authorization from regulatory agencies. Our past experiences in previous companies have been well rewarded when we have followed our Regulatory Science approach to focus on development activities rather than the associated risks of drug discovery.

The Processa Regulatory Science approach was initially developed by Processa's founders 30 years ago when they were formally engaged by the FDA to conduct regulatory science focused clinical programs that would become the foundation for multiple FDA Guidance documents. Over the years, the Processa Founders have refined this Regulatory Science approach resulting in FDA approvals within almost every New Drug Division of the FDA.

We have invested our time and our own money in Processa and its mission. We don't believe value creation comes from bloated payrolls for executives in the C-suite; it comes from generating compelling clinical data. This is where we are allocating our resources. After

uplisting on the Nasdaq, we demonstrated our personal commitments by limiting the combined cash compensation for our six C-suite members to less than $600k annually. This aligns our interests with our shareholders.

In 2022, our focus continues to be developing our pipeline of drugs to obtain data that would allow us to initiate multiple Phase 3 trials in 2023.

Accomplishments in 2021

Our four major goals at the start of 2021 were simple:

1. Initiate enrollment of PCS499 in our Phase 2B trial for the treatment of ulcerative Necrobiosis Lipoidica (uNL) and enroll enough patients to complete an interim analysis.

   We anticipated enrolling 8-10 patients for a six-month treatment course before the end of 2021. Unfortunately, COVID-19 had a significant impact on our study enrollment and only three patients were enrolled. Patients who have suffered for months or years from the serious but not life-threatening condition of uNL were neither willing to take the risk of contracting a life-threatening case of COVID-19 themselves nor risk passing it on to family members as a result of required visits to our clinical sites. We also experienced having patients scheduled for study screening dying of COVID-19 before screening. Given the low enrollment rate, we expanded our patient recruitment efforts in the second half of 2021. Even with slower than expected enrollment, we should still meet our goal of initiating a Phase 3 pivotal trial in 2023.

2. Initiate enrollment in our Next Generation Capecitabine (PCS6422 and capecitabine combination treatment) Phase 1B trial in Patients with Advanced Refractory Gastrointestinal Tract Tumors and determine if PCS6422 was successfully affecting the metabolism of capecitabine.

   We initiated the trial and successfully completed the first 2 cohorts. The interim analysis of the data from these patients demonstrated that PCS6422 successfully inhibited the metabolism of capecitabine over 24-48 hours after administration of PCS6422 but unfortunately did not inhibit the metabolism throughout the 7 days of capecitabine treatment as desired. The first 2 cohorts provided us with enough information to modify our trial so we can determine more optimal regimens for both PCS6422 and capecitabine. We delayed enrolling additional patients in 2021 until we finalize the modification of our trial, expected to be submitted to FDA in the first half of 2022.

3. Obtain an IND for PCS12852 for the treatment of gastroparesis.

   Many of the drugs that currently address the gastroparesis multibillion dollar market have serious side effects and can only be taken for a short duration of time. The first step to guide the development of PCS12852 is to evaluate the effect of PCS12852 on the gastric emptying rate and the symptoms associated with gastroparesis. An IND was submitted in 2021 and FDA notified us that the Phase 2A trial was safe to proceed. A CRO was selected, sites are being initiated and preparations are underway to begin enrolling patients during the first half of 2022.

4. In-license a drug such as PCS3117 that is closer to Phase 3 and NDA than other drugs within our pipeline but still possess a “de-risked” development path.

   PCS3117 was in-licensed in 2021. PCS3117 is a chemotherapeutic agent similar to currently FDA approved Gemcitabine. PCS3117 has been shown in preliminary studies to successfully treat pancreatic cancer patients that are both resistant and responsive to Gemcitabine. The drug has received Orphan Designation for the treatment of pancreatic cancer. Our development plan for PCS3117 has been defined with alternate routes to approval depending on the results of the next studies we plan to conduct. We have also begun to define and develop biomarker assays that would help us identify patients likely to have a better response to PCS3117 than Gemcitabine.

In addition to these achievements, in February 2021 we completed a private placement sale of 1,321,132 shares of common stock at a purchase price of $7.75 per share for a total of $10.2 million; and have expanded our development team with the hiring of four highly qualified individuals.

Milestones for 2022

As we enter 2022, we have sufficient cash to complete the three clinical trials briefly described below (i.e., PCS499 Phase 2B, PCS6422 Phase 1B, PCS12852 Phase 2A) and the biomarker assay development for PCS3117. If we see opportunities in the financing market, we could also strategically improve our cash position by nominal use of our ATM financing.

1. PCS499 – With the expanded enrollment efforts, we expect to complete our Phase 2B interim analysis and complete full enrollment of all patients in 2022. This will allow us to complete the final report on the Phase 2B trial in 2023 and communicate with FDA as we initiate our Phase 3 trial in 2023.

2. PCS6422 – We are finalizing the revised Phase 1B protocol for “Next Generation Capecitabine” to first determine a more optimal DPD inhibition regimen for PCS6422 followed by defining the Maximum Tolerated Dose of capecitabine for the more optimal PCS6422 DPD inhibition regimen. The revised protocol will be submitted to the FDA in the first quarter of 2022 with the plan to restart recruitment in the first half of 2022. We are expanding our recruitment efforts for this program to complete recruitment of all patients for this trial by the end of 2022.

3. PCS12852 – The Phase 2A trial in gastroparesis patients has been initiated with enrollment expected to begin soon. This study will enroll 24 patients with enrollment completion expected by the end of 2022.

4. PCS3117 – We have started the development of biomarkers for PCS3117 in pancreatic cancer patients and expect to complete this during the first half of 2022. Following completion of the biomarker assays, we plan to begin a clinical trial evaluating the biomarker’s role in PCS3117 treatment.

5. PCS11T – The IND enabling development program for the treatment of small cell lung cancer and gastrointestinal cancer is being finalized for PCS11T with the expectation that these studies could be initiated in 2022.

6. All Programs – We hope to identify additional regulatory paths to accelerate development and reduce development risks for some of our pipeline drugs.

In summary, at the core of our operation is the application of our Regulatory Science approach, which in essence is about designing and refining the development programs and clinical studies given the data at hand and conducting development programs through the eye of an FDA reviewer whose primary goal is to evaluate approvability through the "Benefit/Risk" profile of a drug. With our achievements in 2021 and expected progress in 2022, in addition to evaluating the data as a scientist/clinician, we will utilize our experience with the FDA to evaluate the studies, data and programs as an FDA reviewer would, allowing the program for each drug to be more efficiently developed while de-risking the program at each step.

If you have any questions about our programs, contact Michael Floyd (mfloyd@processapharma.com) or Patrick Lin (plin@processapharma.com).

We look forward to an exciting 2022!

Sincerely,

David Young Pharm.D., Ph.D.
CEO, Processa Pharmaceuticals

About Processa Pharmaceuticals, Inc.

The mission of Processa is to develop products with existing clinical evidence of efficacy for patients with unmet or underserved medical conditions who need treatment options that improve survival and/or quality of life. The Company uses these criteria for selection to further develop its pipeline programs to achieve high-value milestones effectively and efficiently. Active clinical pipeline programs include: PCS6422 (metastatic colorectal cancer and breast cancer), PCS499 (ulcerative necrobiosis lipoidica) and PCS12852 (gastroparesis/GI motility). The members of the Processa development team have been involved with more than 30 drug approvals by the FDA (including drug products targeted to orphan disease conditions) and more than 100 FDA meetings throughout their careers. For more information, visit the company's 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 registration statement relating to the securities being sold in this offering, which identifies important risk factors which could cause actual results to differ from those contained in the forward-looking statements.

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