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Processa Pharmaceuticals

Processa Pharmaceuticals Issues Letter to Shareholders Highlighting Corporate Strategy, Drug Pipeline, and Outlook

HANOVER, MD, Nov. 29, 2023 (GLOBE NEWSWIRE) -- Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) ("Processa" or the "Company"), a clinical-stage pharmaceutical company now focused on developing the next generation of chemotherapeutic drugs to improve the efficacy and safety for patients suffering from cancer, announces that CEO George Ng has issued a letter to shareholders.

Dear Processa Pharmaceuticals Shareholders:

Following Processa's business pivot to focus on oncology drug product development, I was recently appointed as Processa's CEO, and I thought it would be helpful for investors to get a corporate update from a new voice at the Company. I joined Processa not with the intent to change the Company's current strategic course, but rather, I intend to apply my background and expertise to complement the strong clinical and regulatory development backgrounds of the current Processa team. Earlier in 2023, the strategic decision was made to focus on development of the Company's Next Generation Chemotherapy (NGC) agents. That will not change under my direction, and much of my experience is in oncology and leading business transactions.

Even with the advent of immuno-oncology and other oncology drugs and treatments, chemotherapy drugs still remain an important and viable treatment option (as Straits Research estimated the chemotherapy market was $9.5B in 2022 and will grow at 7.1% CAGR through 2031). However, many issues and limitations are associated with the use of chemotherapy. Many patients simply cannot tolerate a chemotherapy dose high enough to benefit from its use due to chemotherapy's toxic side effects. This requires the oncologist to reduce the dosage level or stop chemotherapy treatment entirely. In many cases, efficacy suffers when the planned dosing can't be tolerated by the patients and lowering dosage levels to mitigate the drug's toxicity just isn't sufficient to justify the lower quality of life patients experience.

I think Processa can address these shortcomings with chemotherapy by providing patients with potentially safer and more effective chemotherapy treatments through the pursuit of our Next Generation Chemotherapies (NGCs). Moreover, if we are successful at reducing the typically dose limiting side effect profiles of chemotherapy, we may be able to open chemotherapy to broader patient populations, potentially including the pediatric and elderly populations that have historically been unable to tolerate typical chemotherapy treatments, and expand the chemotherapy market.

Forward Looking Vision

Our vision at Processa is to improve already-approved and widely used cancer-killing chemotherapies that have a proven history of therapeutic success and/or the safety profiles

by modifying their metabolism and/or distribution. How we believe we can accomplish this requires we get into our science, which is beyond the scope of this update, as our mechanisms of action vary a bit across our pipeline portfolio. Nonetheless, preliminary pre-clinical and clinical data thus far is encouraging, though certainly more clinical work needs to be done.

Experienced Team
Working in our favor are deep management and R&D teams that have significant and direct experience in clinical drug development. With our team's Regulatory Science Approach, we are aligned with the FDA's new Project Optimus Oncology Initiative that requires the Optimal Dosage Regimen (ODR) to be developed for each cancer drug. Processa's founders, through their Regulatory Science Approach, have developed a similar approach to drug development over the last 35 years that looks to balance safety and efficacy. Furthermore, the Company's founders have been involved with over 30 FDA drug approvals across multiple indications. Thus, we feel confident in navigating this relatively new FDA clinical pathway in the hopes of developing chemotherapy agents with fewer side effects, greater efficacy, and a more efficient approval process.

De-Risked and Diverse Pipeline
Our current pipeline consists of three separate NGCs in development:

1. NGC-Capecitabine (PCS6422) – targeted at colorectal, pancreatic, and other solid tumor cancers
2. NGC-Gemcitabine (PCS3117) – targeted at pancreatic, gall bladder, and non-small cell tumor cancers
3. NGC-Irinotecan (PCS11T) – targeted at pancreatic, ovarian, lung, colorectal, and other cancers

It is important to recognize that each of the respective underlying chemotherapy agents in each NGC candidate are already approved, are on the market (*i.e*. capecitabine, gemcitabine, and irinotecan), and are used across multiple cancer indications, with each generating between $500 million - $1 billion in worldwide revenue. We estimate over 200,000 patients are diagnosed in the U.S. each year with a cancer type that can be treated by one of these drugs. Although we currently already have extensive patent protection for our NGC assets (*e.g*., for NGC-Capecitabine (PCS6422), potential patent term extends to at least 2043), we will continue to pursue an aggressive patenting strategy for all of our assets and are optimistic that we can build additional intellectual property (IP) barriers around our technology as we develop our drug products and technologies. Importantly, our pipeline of NGC candidates are New Chemical Entities (NCEs), and we are not pursuing the 505(b)(2) regulatory pathways for regulatory approval, resulting in stronger regulatory protection and IP position for each candidate.

The current status and upcoming near-term potential milestones for each of our NGCs is follows:

NGC-Capecitabine (PCS6422)

- Phase 1b study enrollment is expected to be completed by early 2024
- Assessment of the safety profile of NGC-Cap in totality across all cohorts is expected to be completed by mid 2024

- Discussion with FDA to determine Phase 2 study design expected by year-end 2023
- With FDA feedback, dose regimen to be used in Phase 2 study is expected to be finalized by mid-2024
- Filing of Phase 2 study to the IND is expected by mid-2024
- Start of patient enrollment in Phase 2 study is expected in mid-2024

NGC-Gemcitabine (PCS3117)

- Analysis of existing Phase 2 data from patients with pancreatic cancer under the Project Optimus framework is expected to be completed in early 2024
- Discussion with the FDA to determine Phase 2b/3a study design expected in the first half of 2024

NGC-Irinotecan (PCS11T)

- Analysis of existing pre-clinical data in animals to develop a drug development roadmap is expected to be completed in early 2024
- Initiate sourcing of drug substance and product manufacturing sites expected in 2024

Stable Financial Affairs and Business Development Opportunities
Of course, the clinical timelines I laid out for our pipeline assume that we have sufficient funding in place. At September 30, 2023 we had $6.9 million in cash, which we believe is sufficient to complete our current Phase 1B study for NGC-Cap and fund our continued operations into the second half of 2024. We are working to supplement our cash position by out-licensing our non-NGC assets (in particular, PCS12852). Earlier this year we reported positive top-line Phase 2a results with PCS12852 in patients with gastroparesis (a digestive disorder) and are optimistic that we can monetize this asset in some fashion to supplement our current cash balance.

In conclusion, given our Forward Looking Vision, Experienced Team, De-Risked and Diversified Pipeline, Stable Financial Affairs and Business Development Opportunities, I feel that Processa is well-positioned for success and is uniquely positioned to disrupt and expand current chemotherapy and oncology therapeutics. To that end, we are looking forward to our upcoming meeting with the FDA and to potentially releasing top-line data during the second half of December. Regarding Processa's pivot to focus on oncology drug development, change forces adaptation that can be stewarded by effective leadership. My intention as the new CEO is to promote, encourage, and facilitate advancement in the areas in which we excel. With our potentially revolutionary NGC drug products, Processa is poised to be a global leader in chemotherapy and oncology, and I am incredibly honored to have the opportunity to lead Processa through this transition and work to create shareholder value. In this regard, thank you to all our shareholders that continue to support our Company.

Sincerely,

George Ng
CEO, Processa Pharmaceuticals

About Processa Pharmaceuticals, Inc.

Processa is a clinical stage pharmaceutical company focused on developing the Next

Generation Chemotherapy (NGC) drugs to improve the safety and efficacy of cancer treatment. By combining Processa's novel oncology pipeline with proven cancer-killing active molecules and the Processa Regulatory Science Approach as well as experience in defining Optimal Dosage Regimens for FDA approvals, Processa not only will be providing better therapy options to cancer patients but also increase the probability of FDA approval for its Next Generation Chemotherapy (NGC) drugs following an efficient path to approval. Processa's NGC drugs are modifications of existing FDA-approved oncology drugs resulting in an alteration of the metabolism and/or distribution of these FDA-approved drugs while maintaining the existing mechanisms of killing the cancer cells. The company's approach to drug development is based on more than 30 years of drug development expertise to efficiently design and conduct clinical trials that demonstrate a positive benefit/risk relationship. The Processa team has a track record of obtaining over 30 approvals for indications across almost every division of FDA. Using its proven Regulatory Science Approach, the Processa Team has experience defining the Optimal Dosage Regimen using the principles of the FDA's Project Optimus Oncology initiative. The advantages of Processa's NGCs are expected to include fewer patients experiencing side effects that lead to dose discontinuation, more significant cancer response and a greater number of patients -- in excess of 200,000 for each NGC drug -- who will benefit from each NGC drug. Currently under development are three next generation chemotherapy oncology treatments: Next Generation Capecitabine (PCS6422 and capecitabine to treat metastatic colorectal, gastrointestinal, breast, pancreatic, and other cancers), Next Generation Gemcitabine (PCS3117 to treat pancreatic, lung, ovarian, breast, and other cancers), and Next Generation Irinotecan (PCS11T to treat lung, colorectal, gastrointestinal, pancreatic, and other cancers).

For more information, visit our website atwww.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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