

October 9, 2018



# CytoDyn Announces Strategy to Complete Development of Novel ProstaGene Gene-based Prostate Cancer Prognostic Test

## **PCaTest demonstrated superior ability to predict outcomes versus other genetic-based prostate cancer prognostic tests in three data sets**

VANCOUVER, Washington, Oct. 09, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), CytoDyn unveils its strategy to complete development of PCaTest, a novel gene-based prognostic test for prostate cancer developed by ProstaGene. Following the completion of CytoDyn's previously announced proposed acquisition of assets from ProstaGene, the Company intends to initiate a clinical study designed to further demonstrate the superiority of the PCaTest compared with current genetic tests in predicting outcomes of individuals with prostate cancer. Study results are expected within four months from the commencement of the clinical study. In August 2018, CytoDyn announced a definitive agreement to acquire substantially all of the assets of ProstaGene. The closing of the proposed ProstaGene asset acquisition is subject to various closing conditions and is expected to close during the fourth quarter of 2018.

"The PCaTest has shown a three- to four-times superior hazards ratio, the predictor of outcome, in its ability to distinguish patients with prostate cancer facing good versus poor outcomes in data sets from three studies," said Richard Pestell, M.D., Ph.D., CytoDyn's Interim Chief Medical Officer and developer of the PCaTest. "Results from studies are promising, as recent evidence has raised concern about the ability of current genetic tests to distinguish whether an individual's prostate cancer will grow slowly or aggressively. This essential information about the cancer's genetic makeup is used by patients and physicians in treatment decision-making for individuals with this disease."

The current management of prostate cancer involves the use of a prostate-specific antigen (PSA) test that screens for elevated PSA in blood. The tests can provide warning signs of prostate cancer, but elevated PSA is not a sure sign of cancer with only a portion of those actually diagnosed with the disease. Patients with serially elevated PSA are typically recommended for prostate biopsy, which requires inserting a needle to the prostate with typically 12 extracted tissue samples for the standard testing for disease detection. Genetic tests for prostate cancer outcomes, such as the PCaTest, can be performed on a single tissue sample.

"Our plan is to complete development of the PCaTest relatively quickly and at a minimal cost to CytoDyn and to file for U.S. Food and Drug Administration (FDA) approval," said Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive Officer. "We will gain access to the PCaTest, in addition to the technologies and patents for CCR5 antagonists in

metastatic cancer from ProstaGene, with completion of this acquisition expected in the near term.”

The PCaTest employs 14 gene biomarker signatures for prognostication and therapeutic substratification of prostate cancer using sophisticated proprietary artificial intelligence algorithms. Results from three clinical studies in a total of 348 patient samples show the test as superior in hazards ratio to five currently marketed genetic-based prostate cancer prognostic tests.

### **About Prostate Cancer**

Prostate cancer is the second most common cancer among American men who face a 1-in-9 lifetime risk for developing the disease, according to the American Cancer Society.

Annually in the U.S., approximately 20 million men are screened with the PSA test and more than 1.3 million prostate biopsy procedures are performed. In guidelines issued in May 2018, the U.S. Prevention Services Task Force, an independent panel of experts that makes recommendations to the American public about preventive services, recommended screening for men between the ages of 55 and 69.

### **About CytoDyn**

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on PRO 140 (Ieronlimab), a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 plays a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor is also implicated in tumor metastasis and in immune-mediated illnesses such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with PRO 140 in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for PRO 140 in combination therapy and plans to complete the filing of a Biological License Application (BLA) in the first quarter of 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with PRO 140 as a once-weekly monotherapy for HIV-infected patients, and plans to initiate a registration-directed study of PRO 140 monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b clinical trial demonstrated that PRO 140 monotherapy can prevent viral escape in HIV-infected patients, with some patients on PRO 140 monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate PRO 140 for the prevention of GvHD and expects to initiate clinical trials with PRO 140 in metastatic triple-negative breast cancer in 2018. More information is at [www.cytodyn.com](http://www.cytodyn.com).

### **Forward-Looking Statements**

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the proposed transaction with ProstaGene, the closing conditions and the likelihood of closing the proposed transaction with ProstaGene, the Company’s clinical focus, and the Company’s current and proposed trials. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,”

“intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. The Company’s forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, the Company urges investors to specifically consider the various risk factors identified in the Company’s Form 10-K for the fiscal year ended May 31, 2018 in the section titled “Risk Factors” in Part I, Item 1A, any of which could cause actual results to differ materially from those indicated by the Company’s forward-looking statements.

The Company’s forward-looking statements reflect its current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. Investors should not place undue reliance on the Company’s forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of the Company’s cash position and the Company’s ongoing ability to raise additional capital to fund its operations, (ii) the Company’s ability to complete its Phase 2b/3 pivotal combination therapy trial for PRO 140 (CD02) and to meet the FDA’s requirements with respect to safety and efficacy to support the filing of a Biologics License Application, (iii) the Company’s ability to meet its debt obligations, if any, (iv) the Company’s ability to identify patients to enroll in its clinical trials in a timely fashion, (v) the Company’s ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of the Company’s clinical trials, including the possibility of unfavorable clinical trial results, (viii) the market for, and marketability of, any product that is approved, (ix) the existence or development of vaccines, drugs, or other treatments for infection with HIV that are viewed by medical professionals or patients as superior to the Company’s products, (x) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xi) general economic and business conditions, (xii) changes in foreign, political, and social conditions, and (xiii) various other matters, many of which are beyond the Company’s control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by the Company’s forward-looking statements.

The Company intends that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act of 1933, as amended, to the extent applicable. Except as required by law, the Company does not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, the Company does not undertake any responsibility to update investors upon the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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