November 29, 2018

CytoDyn's Prostate Cancer Prognostic Test Demonstrates Substantial Added Value to Gleason Score in Predicting Patient Outcomes

Results of clinical study comparing PCaTest and Gleason test scores further support FDA filing

VANCOUVER, Washington, Nov. 29, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY) announces that results from a recent clinical study showed that CytoDyn's PCaTest provides substantial additive discriminative value for predicting outcomes of patients diagnosed with prostate cancer compared to the Gleason score, the current standard for prostate cancer diagnosis. The positive clinical data from two groups totaling 218 patients and followed for 10 years adds to three prior clinical studies conducted in more than 350 patients that demonstrated a high predictive value for CytoDyn's PCaTest in determining outcome of men diagnosed with prostate cancer. The new findings support the Company's strategy for seeking U.S. Food and Drug Administration (FDA) approval for the PCaTest.

Prostate cancer is third only to nonmelanoma skin cancer and lung cancer as the leading cause of cancer and cancer death, respectively, in men in the U.S. Worldwide, an estimated 1.6 million new cases of prostate cancer are diagnosed and 366,000 prostate cancer deaths are reported annually, making it the most commonly diagnosed cancer in men.

Richard Pestell, M.D., Ph.D., F.A.C.P., M.B.A., CytoDyn's Chief Medical Officer and developer of the PCaTest, said, "Unfortunately, current tests not able to precisely determine whether an individual's cancer will result in death if not treated aggressively. On the other hand, aggressive treatment for prostate cancer has significant long-term side effects that can include incontinence, erectile dysfunction and dribbling, and should be avoided if possible. The PCaTest uses a proprietary artificial intelligence approach designed to yield a more accurate prognostic result. In essence, we believe the test is designed to identify with greater certainty patients whose lives are at risk if they don't have their prostate removed. The test is being developed to show gene signatures can help guide patients and their doctors to make better informed decisions about treatment."

"These positive clinical results provide critical information that support our strategy of completing development of the PCaTest quickly and cost-effectively and filing to seek FDA approval," said Dr. Nader Pourhassan, Ph.D., CytoDyn's President and Chief Executive

Officer. “This new study adds important data that is additive to the high predictive value of the PCaTest has shown in past studies compared with currently available genetic tests.

“We are excited about about the potential of the Prostate Cancer genetic testing platform including the PCaTest that we gained through the acquisition of ProstaGene, which is in addition to the valuable intellectual property and patents for CCR5 antagonists related to metastatic cancer,” Dr. Pourhassan added.

About CytoDyn’s PCaTest Study

This retrospective clinical study assessed patients followed for more than 10 years after the initial diagnosis of prostate cancer. The purpose of the study was to determine if CytoDyn’s PCaTest would improve the prediction of whether prostate cancer would lead to death. Analysis was conducted of 3 subgroups based on Gleason score. Patients with a low Gleason score usually undergo continued observation, while patients with a high Gleason score typically have a prostatectomy. The study was designed to evaluate an approach for patients with an indeterminate/intermediate Gleason score.

The study focused on patients with a Gleason score of 7, considered indeterminate/intermediate, and classified this group as the baseline measure. Consistent with the Gleason scoring system, all the patients in this population had a prostatectomy. Using the Cox Proportional Hazards model, the addition of the PCaTest. Score was able to further characterize patients with indeterminate/intermediate Gleason score as low risk or high risk. Patients with high risk scores identified an elevated risk of recurrence in population 1 (HR=9.44, $p=2.4x10^{-5}$) and population 2 (HR=3.43, $p=7.2x10^{-3}$). The results show CytoDyn’s prognostic test as providing substantial additional value beyond the current standard of care in determining outcome.

About Prostate Cancer

In 2008, the United States Preventive Services Task Force (USPSTF) recommended against screening men aged 75 years and older. In 2013, prostate cancer screening of men in the U.S. decreased by 18%. Furthermore, management of prostate cancer has increasingly deployed either “watchful waiting” or “active surveillance” to avoid unnecessary surgery (prostatectomy) and radiation and/or chemotherapy with its attendant side effects. Since 2004, there has been a 72% rise in metastatic prostate cancer compared. In order to more precisely guide therapeutic options for men diagnosed with prostate cancer through histological analysis of the prostate biopsy, additional predictive tools have been developed including gene signature-based tests. Several gene signature-based tests have been developed and are currently reimbursed by U.S. health providers. CytoDyn’s Prognostic test compared more than favorably with current tests in the market place.

About CytoDyn

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab (PRO 140), 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 leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for leronlimab 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 leronlimab as a once-weekly monotherapy for HIV-infected patients and plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab 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 leronlimab monotherapy can prevent viral escape in HIV-infected patients, with some patients on leronlimab monotherapy remaining virally suppressed for more than four years. CytoDyn is conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and recently received FDA approval to initiate a clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is available at **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 predictive value or benefit from the Company's prostate cancer prognostic test, 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, and in our Form 10-Q for the quarterly period ended August 31, 2018 in the section titled "Risk Factors" in Part II, 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 leronlimab (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 obtain FDA approval of PCaTest for use with prostate cancer patients; (iv)the Company's ability to meet its debt obligations, if any, (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Company's ability to achieve approval of a marketable product, (vii) design, implementation and

conduct of clinical trials, (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (ix) the market for, and marketability of, any product that is approved, (x) 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, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) 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.

CONTACTS:
Investors:
LHA Investor Relations
Jody Cain
310-691-7100
jcain@lhai.com

Source: CytoDyn Inc.