July 12, 2018

CytoDyn to Expand Strategic Focus with PRO 140 to Cancer and Immunologic Disorders

- **Announces non-binding Letter of Intent to acquire CCR5-focused cancer company ProstaGene LLC**
- **Maintains commitment to advancing PRO 140 clinical programs in HIV and graft-versus-host disease**
- **Advancing plans to submit BLA for PRO 140 in combination therapy for HIV**

VANCOUVER, Washington, July 12, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB:CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody, announces a strategic expansion of its clinical focus to include the evaluation of PRO 140 in certain cancers and immunological indications where CCR5 antagonism has shown initial promise. In connection with such expansion, the Company has signed a non-binding letter of intent regarding the potential acquisition of ProstaGene LLC, a privately held company focused on prostate cancer diagnostics and therapeutics aimed at blocking cancer metastasis by blocking CCR5. At the same time, CytoDyn remains committed to advancing its clinical programs with PRO 140 in human immunodeficiency virus (HIV) and graft-versus-host disease (GvHD), and is continuing with its previously announced plans to submit a Biologics License Application (BLA) for PRO 140 as a combination therapy for HIV.

“We are beginning an exciting new era at CytoDyn that builds upon the scientific promise of PRO 140 and the expansion of our clinical focus,” said Anthony Caracciolo, CytoDyn’s Chairman. “We believe it is in the best interest of our shareholders, patients and the medical community to advance the evaluation of PRO 140 in these new indications, while pursing partnership opportunities to support all of our development programs. Given our substantial and growing clinical experience with PRO 140, we have confidence in its safety and efficacy profiles. Recent studies indicate potential opportunities for PRO 140 in multiple indications beyond HIV where CCR5 antagonism may be beneficial. These include oncology, immunology, transplant rejection, chronic inflammation, autoimmunity, and nonalcoholic steatohepatitis (NASH), among others.”

The scientific rationale underlying this expanded strategic initiative is the ability of PRO 140 to selectively target the CCR5 receptor. Research conducted by CytoDyn, the laboratories of Richard G. Pestell, M.D., Ph.D., Chief Executive Officer of ProstaGene and President of the Pennsylvania Cancer and Regenerative Medicine Research Center and his collaborators, and others has shown that selectively blocking the CCR5 receptor and the interaction of the chemokine CCL5/RANTES is crucial in modulating immune cell trafficking. In addition, the CCR5 receptor is believed to be vital in cancer cell invasion and metastasis.

“When we evaluated PRO 140 last year in our models of metastatic breast cancer, we were excited to see that the monoclonal antibody detected CCR5 on the tumor cells and blocked their invasiveness, suggesting its potential to block certain metastatic cancers,” said Dr. Pestell. “I am very excited to have ProstaGene team with CytoDyn to further explore the potential of PRO 140 as an important addition to the therapeutic arsenal against aggressive cancers.”

“We are very pleased to be building on our relationship with Dr. Pestell and his team at ProstaGene, who have been focused on understanding the relationship of the CCR5 receptor to cancer metastasis,” Mr. Caracciolo commented. “We look forward to working toward the proposed acquisition of the company’s intellectual property and other assets over the coming months.”

As part of the potential transaction with ProstaGene LLC, it is expected that Dr. Pestell will join the CytoDyn Board of Directors at the closing of the proposed transaction.

Previous clinical and preclinical studies with PRO 140 and other CCR5 antagonists have demonstrated that blocking CCR5 receptors has potential applications in multiple cancer types. Preclinical research has also shown that treatment with CCR5 inhibitors can inhibit metastasis and invasion of prostate, breast and colon cancers, including patients with treatment-resistant colon cancer. Results of a recent preclinical study conducted in collaboration with the laboratory of Dr. Pestell, and announced by CytoDyn, established that PRO 140 was able to detect CCR5 on metastatic human breast cancer cells and block their invasiveness as effectively as small molecule CCR5 inhibitors.

The contemplated transaction is subject to completion of due diligence review, customary definitive documentation, deal structure and requisite corporate and regulatory approval. The final terms of the proposed acquisition will be available upon the execution of the definitive documents.

About ProstaGene
ProstaGene is a biotechnology start-up company that is developing technology based on issued patents of the Founder, Dr. Richard G. Pestell. ProstaGene integrates proprietary molecular diagnostics with novel therapeutic screening and commercial experience in order to develop novel treatments for cancer utilizing its gene-based prostate cancer testing technology and its cancer metastasis prevention and treatment technology. It has issued patents in the U.S.A. and Australia and is prosecuting patents covering its technologies in the United States and major countries around the world. ProstaGene also maintains its gene signature test details as trade secrets. For more information on ProstaGene, please visit http://prostagene.com.

About PRO 140
PRO 140 belongs to a new class of HIV/AIDS therapeutics – viral-entry inhibitors – that is intended to protect healthy cells from viral infection. PRO 140 is a humanized IgG4 monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter T cells. PRO 140 blocks the predominant HIV (R5) subtype entry into T cells by masking this required co-receptor, CCR5. Importantly, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. PRO 140 does not have agonist activity toward CCR5 but does have antagonist activity to CCL5, which is a central mediator in inflammatory diseases. PRO 140 has been the subject of seven clinical trials, each

demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. PRO 140 has been designated a “fast track” product by the FDA. The FDA also granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD). The PRO 140 antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements compared with daily drug therapies currently in use.

About CytoDyn

CytoDyn is a biotechnology company focused on the clinical development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV infection, cancer and inflammatory diseases. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has completed Phase 2 clinical trials with demonstrated antiviral activity in humans and is currently in Phase 3 development. PRO 140 blocks the HIV co-receptor CCR5 on T cells, which prevents viral entry. Clinical trial results thus far indicate that PRO 140 does not negatively affect the normal immune functions that are mediated by CCR5. Results from seven Phase 1 and Phase 2 human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. A recent Phase 2b clinical trial demonstrated that PRO 140 can prevent viral escape in patients during several months of interruption from conventional drug therapy. CytoDyn intends to continue to develop PRO 140 as a therapeutic anti-viral agent in persons infected with HIV and to pursue cancer, inflammatory and other non-HIV indications where CCR5 and its ligand CCL5 may be involved. For more information on the Company, please visit 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 potential acquisition, the likelihood of closing the potential transaction, our clinical focus, and our 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. Our 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, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended May 31, 2017 in the section titled “Risk Factors” in Part I, Item 1A and in our Form 10-Q for the quarterly period ended February 28, 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 our forward-looking statements.

Our forward-looking statements reflect our 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. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our 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) our ability to meet our

debt obligations, if any, (iv) our ability to identify patients to enroll in our clinical trials in a timely fashion, (v) our ability to achieve approval of a marketable product, (vi) design, implementation and conduct of clinical trials, (vii) the results of our 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 the Human Immunodeficiency Virus that are viewed by medical professionals or patients as superior to our 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 our 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 our forward-looking statements.

We intend 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, to the extent applicable. Except as required by law, we do 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, we do not undertake any responsibility to update you on 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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