New Research Supports Potential for CytoDyn’s PRO 140 to Inhibit Breast Cancer Metastasis

Study conducted in collaboration with world-renowned oncologist Dr. Richard G. Pestell shows ability of PRO 140 to block cancer invasion into healthy cells in surrogate assay for metastatic breast cancer

VANCOUVER, Washington, June 26, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB:CYDY), announces that findings from a preclinical study in a surrogate assay for metastatic breast cancer showed that PRO 140, a novel humanized CCR5 monoclonal antibody, detected CCR5 on human breast cancer cells and blocked their invasion as effectively as small molecule CCR5 inhibitors. The study was conducted in collaboration with prominent oncologist Richard G. Pestell, M.D., Ph.D., President of the Pennsylvania Cancer and Regenerative Medicine Research Center, Baruch S. Blumberg Institute and Pennsylvania Biotechnology Center.

“I contacted CytoDyn last year about conducting studies with PRO 140 in metastatic breast and prostate cancer after my published research, and studies by others, had shown promising results with small molecule CCR5 antagonists in multiple cancer indications,” said Dr. Pestell. “While these are early-stage study results, it’s encouraging to find that PRO 140 detected CCR5 on highly metastatic human breast cancer cells and blocked their invasiveness. The blocking of breast cancer invasion with PRO 140 was as effective as with small molecule CCR5 inhibitors in our prior published studies. Our previous studies showed small molecular CCR5 inhibitors effectively block metastasis of human breast cancer cells to the lungs, and blocked prostate cancer cell metastasis to the bones and the brain.”

Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer, commented: “We are very encouraged that these results show that PRO 140 has the potential to block metastatic breast cancer. Based upon our human studies in HIV patients, we believe PRO 140, if approved, may offer less frequent dosing and an improved safety profile when compared to other small molecule CCR5 antagonists. This reaffirms our belief that PRO 140 may have significant opportunities beyond HIV and GvHD. We are very pleased to be collaborating in this work with Dr. Pestell and are encouraged by these findings with PRO 140.”

CCR5 and CCL5 are potential markers for metastatic cancer, and their interaction leads to increased cancer cell invasion and metastasis. Recent research by Dr. Pestell and others has shown that treatment with CCR5 inhibitors can inhibit metastasis and invasion of prostate cancer, breast cancer and colon cancer, including patients with colon cancer resistant to prior treatments. Thus, blocking CCR5/CCL5 interaction with PRO 140 may prove a useful therapeutic strategy to prevent metastasis and control cancer progression.

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 towards 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. 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 non-HIV, inflammatory 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 our current and proposed trials and studies and their enrollment, results, costs and completion. 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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