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CytoDyn Announces Strong Preclinical Results Using PRO 140 in Human Colon Carcinoma

CytoDyn will file an IND, along with a proof-of-concept protocol for colon cancer

PRO 140 shown effective in inhibiting human colon carcinoma growth

VANCOUVER, Washington, Aug. 15, 2018 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that PRO 140 (leronlimab) has been shown effective at inhibiting the growth of a human colon carcinoma cell line (SW480) in a prominent mouse model. The results were statistically significant and provide the basis for filing an Investigative New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for a clinical trial in colon carcinoma patients.

Two different strains of immunoincompetent mice were used to grow SW480 human tumor cells and different doses of PRO 140 were used in these studies. The SW480 cell line was derived from a patient with colon adenocarcinoma and, like many human cancers, was CCR5-positive. PRO 140 extended the life of treated mice and decreased tumor growth compared to control mice by greater than 50%, which was statistically significant. These results were dose dependent and were repeated in separate experiments. Current ongoing preclinical studies are defining the mechanisms involved in the anti-tumor efficacy of PRO 140.

“We have been conducting these preclinical studies over the past year to better document the activity of PRO 140 against CCR5-expressing human tumors,” stated Nader Pourhassan, Ph.D., CytoDyn President and Chief Executive Officer. “We believe that CCR5 is a crucial receptor in the growth and invasiveness of human malignancies, and these studies support that premise. Along with our recent announcement regarding the potential of PRO 140 in metastatic breast cancer, we believe these results in colon cancer further support that PRO 140, if approved, may offer an important potential therapeutic option for patients with breast and colon cancer. We now plan to file an IND within the next few weeks to begin studies of PRO 140 for the treatment of colon carcinoma. We will also continue to explore the biological pathways involving CCR5 to identify other potential therapeutic opportunities for PRO 140.”

CytoDyn also noted that upon the closing of its proposed acquisition of ProstaGene, Richard G. Pestell, Ph.D., M.D., Chief Executive Officer of ProstaGene and President of the Pennsylvania Cancer and Regenerative Medicine Research Center, is expected to be appointed CytoDyn’s Chief Medical Officer.

“We look forward to Dr. Pestell joining our team and leveraging his decades of research with the CCR5 receptor as we further explore opportunities for PRO 140 in cancer, immunology and autoimmune disorders,” added Dr. Pourhassan.

About PRO 140
PRO 140 is a humanized IgG4 monoclonal antibody that blocks CCR5, a cellular receptor that plays multiple roles with implications in HIV infection, tumor metastasis, and immune signaling.

In the setting of HIV/AIDS, PRO 140 belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. At the same time, PRO 140 does not appear to interfere with the normal function of CCR5 in mediating immune responses. 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 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.

In the setting of cancer, research has shown that CCR5 plays a central role in tumor invasion and metastasis and that an increased CCR5 is an indicator of disease status in several cancers. Moreover, researchers have shown that drugs that block CCR5, including PRO 140, can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with PRO 140 in the cancer setting and plans to initiate Phase 2 human clinical trials when appropriate.

The CCR5 receptor also plays a central role in modulating immune cell trafficking to sites of inflammation and it is crucial for the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others have shown that blocking CCR5 using a chemical inhibitor can reduce the clinical impact of acute GvHD without significantly affecting the engraftment of transplanted bone marrow stem cells. CytoDyn is currently conducting a Phase 2 clinical study with PRO 140 to further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and that blocking this receptor from recognizing certain immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted orphan drug designation to PRO 140 for the prevention of graft-versus-host disease (GvHD).

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 the proposed transaction with ProstaGene, 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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