CytoDyn’s PRO 140 Monoclonal Antibody Prevents Graft-Versus-Host Disease in Model of Bone Marrow Stem Cell Transplantation

*PRO 140 Currently in Phase 2 Clinical Trial in Leukemia Patients Receiving Bone Marrow Transplants*

*Preclinical Proof-of-Concept Published in Biology of Blood and Marrow Transplantation*

VANCOUVER, Washington, Nov. 14, 2017 (GLOBE NEWSWIRE) -- Newly published research provides preclinical proof-of-concept for the ability of PRO 140, a humanized anti-CCR5 monoclonal antibody under development by CytoDyn Inc. (OTCQB:CYDY), to effectively block the development of graft-versus-host disease (GvHD), a potentially lethal complication of bone marrow stem cell (BMSC) transplantation. CytoDyn is currently enrolling patients in a Phase 2 clinical trial with PRO 140 for the prevention of GvHD in leukemia patients undergoing BMSC transplantation.

The new publication shows that when immunocompromised mice transplanted with human BMSCs received PRO 140 at a dosing schedule that approximates that being used in the ongoing human clinical trial, the mice showed successful engraftment of human hematopoietic (blood forming) cells without any signs of GvHD. At the same time, control mice all exhibited classical signs of GvHD and none survived (p<0.01). A 10-fold reduction in PRO 140 dose still showed a significant inhibitory effect on GvHD in treated mice, but to a lesser extent.

The study (click on link) by Denis R. Burger, Ph.D., CytoDyn Chief Science Officer, and Daniel Lindner, M.D., Ph.D. of the Department of Translational Hematology and Oncology Research, The Cleveland Clinic, has been published online in the peer-reviewed journal, *Biology of Blood and Marrow Transplantation*. (Also see: [http://www.bbmt.org/article/S1083-8791(17)30810-8/fulltext](http://www.bbmt.org/article/S1083-8791(17)30810-8/fulltext))

“This research provided CytoDyn with strong rationale for exploring the use of PRO 140 in its second clinical indication, the prevention of GvHD in BMSC transplantation, following our focus on the treatment of HIV infection,” said Dr. Burger. “GvHD is a serious complication that limits the use of BMSC transplantation in patients with blood cancers. The potential of PRO 140 to prevent this life-threatening condition could help extend the use of BMSC transplantation, an important and effective therapy, to more patients.”
PRO 140 targets the CCR5 receptor, a molecule that modulates the immune cell trafficking crucial for the development of acute GvHD and other inflammatory conditions. Previous 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 BMSCs. This new study with PRO 140 further supports 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.

About GvHD

Graft-versus-host disease is a risk when patients receive bone marrow stem cells donated from another person. GvHD occurs when the donor’s immune cells attack the patient’s normal tissues (skin, liver, gut). GvHD can be acute or chronic. Its severity depends on the differences in tissue type between patient and donor. Acute GvHD can occur soon after the transplanted cells begin to appear in the recipient and can range from mild to severe and can be life-threatening. Certain immunosuppressive drugs may help prevent or lessen GvHD. However, GvHD doesn’t always respond to these treatments, and it can still result in fatal outcomes. Furthermore, many deaths related to GvHD occur because of infections that develop in patients whose immune systems are suppressed by such drugs.

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 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, 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 CD02 combination trial 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, (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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