CytoDyn to Expand Clinical Applications for PRO 140 Beyond Therapy for HIV

Graft Versus Host Disease in Bone Marrow Transplantation to be the Next Clinical Indication

VANCOUVER, Wash., June 24, 2015 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating human immunodeficiency virus (HIV) infection, today announced that recent Company research data has expanded the potential clinical indications for PRO 140, now in Phase 3 for the treatment of HIV, to include certain inflammatory diseases, autoimmunity, transplantation and cancer.

The chemokine receptor, CCR5, is expressed on a variety of cells that play a central role in inflammatory responses. The receptor is activated by a chemokine mediator called CCL5, which has been shown to be a central figure in many inflammatory disease processes. Blocking the interaction of CCL5 with the receptor CCR5 is believed to be of therapeutic benefit. The monoclonal antibody PRO 140 targets the chemokine receptor CCR5, binding to it in a way that prevents HIV from using it as an entry gateway without activating the immune function of the receptor. The Company's recent research data indicate that PRO 140 also interferes with activation of the receptor by the mediator CCL5.

The Company has selected a transplantation indication called Graft versus Host Disease (GvHD) as its first non-HIV clinical indication. The CCR5 receptor, the target for PRO 140, is an important mediator of GvHD, especially in the organ damage that is the usual cause of death. The only approved CCR5 inhibitor, Maraviroc, is currently in a Phase 2 study in GvHD and results are expected in 2016. The Company believes that PRO 140 has significant advantages over Maraviroc in more favorable dosing and pharmacokinetics, less toxicity and side effects, and no direct stimulation (agonist activity) of the CCR5 receptor.

Dr. Nader Pourhassan, President and CEO, commented: "CytoDyn is proud to have developed the first self-injectable antibody for the treatment of HIV now at the Phase 3 stage. With this accomplishment in hand, the Company can now move into clinical development on other non-HIV indications for PRO 140. The selection of GvHD as our next clinical program has been an ongoing effort without losing focus on HIV. We have already completed a Key Opinion Leader (KOL) conference on GvHD and are prepared to submit a protocol to the FDA within the next few months, under a new IND (Investigative New Drug application) for this indication."

Dr. Denis R. Burger, Vice Chairman and Immunology Consultant, stated: "The Company has sponsored a research program over the past year gathering data to support the use of PRO 140 in non-HIV indications. The PRO 140 target is the key receptor in the activation and migration of cells of the immune system to sites of inflammation. The results of these studies give us confidence that PRO 140 can have a significant therapeutic benefit in several inflammatory diseases, with GvHD being our first clinical target."

About Graft versus Host Disease

Graft-versus-host disease (GvHD) is a complication that can occur after a stem cell or bone marrow transplant. With GvHD, the newly transplanted donor cells attack the transplant recipient's body. GvHD may occur after a bone marrow or stem cell transplant in which an individual receives bone marrow tissue or cells from a donor. This type of transplant is called allogeneic. The new, transplanted cells regard the recipient's body as foreign. When this happens, the newly transplanted cells attack the recipient's body. GvHD does not occur when an individual receives his or her own cells during a transplant. Before a transplant, tissue and cells from possible donors are tested to determine how closely they match the person having the transplant. GvHD is less likely to occur, or symptoms will be milder, when the match is close. The chance of GvHD is around 30% to 40% when the donor and recipient are related and around 60% to 80% when the donor and recipient are not related. There are two types of GvHD: acute and chronic. Symptoms in both acute and chronic GvHD range from mild to severe. Acute GvHD usually happens within the first six months after a transplant. Chronic GvHD usually starts more than three months after a transplant, and can last a lifetime.
In the United States, in 2011, over 7,500 unrelated donor bone marrow transplants were performed and another 10,000 conducted outside the U.S. One-year survival is now approximately 60% with the most common causes of death being relapse or GvHD. The market in the U.S. is expected to reach $500 million in the next several years.

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 Human Immunodeficiency Virus (HIV) infection. The Company has one of the leading monoclonal antibodies under development for HIV infection, PRO 140, which has finished Phase 2 clinical trials with demonstrated antiviral activity in man and is currently in Phase 3. 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 six 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 weeks 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. For more information on the Company, please visit www.cytodyn.com.

About PRO 140

PRO 140 belongs to a new class of HIV/AIDS therapeutics -- viral-entry inhibitors -- that are intended to protect healthy cells from viral infection. PRO 140 is a fully 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 towards 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 candidate 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 as compared to daily drug therapies currently in use.

Forward-Looking Statements

This press release includes forward-looking statements and forward-looking information within the meaning of United States securities laws, including statements regarding the Company's Phase 3 study and its completion. These statements and information represent CytoDyn's intentions, plans, expectations, and beliefs and are subject to risks, uncertainties and other factors, many beyond CytoDyn's control. These factors could cause actual results to differ materially from such forward-looking statements or information. The words "believe," "estimate," "expect," "intend," "attempt," "anticipate," "foresee," "plan," and similar expressions and variations thereof identify certain of such forward-looking statements or forward-looking information, which speak only as of the date on which they are made.

CytoDyn disclaims any intention or obligation to publicly update or revise any forward-looking statements or forward-looking information, whether as a result of new information, future events or otherwise, except as required by applicable law. Readers are cautioned not to place undue reliance on these forward-looking statements or forward-looking information. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of and expense associated with research, development, regulatory approval, and commercialization of CytoDyn's products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; future clinical trial data on CytoDyn's products and product candidates will be unfavorable; funding for additional clinical trials may not be available; CytoDyn's products may not receive marketing approval from regulators or, if approved, may fail to gain sufficient market acceptance to justify development and commercialization costs; competing products currently on the market or in development may reduce the commercial potential of CytoDyn's products; CytoDyn, its collaborators or others may identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, or other adverse events.

CytoDyn is also subject to additional risks and uncertainties, including risks associated with the actions of its corporate, academic, and other collaborators and government regulatory agencies; risks from market forces and trends; potential product liability; intellectual property litigation; environmental and other risks; and risks that current
and pending patent protection for its products may be invalid, unenforceable, or challenged or fail to provide adequate market exclusivity. There are also substantial risks arising out of CytoDyn's need to raise additional capital to develop its products and satisfy its financial obligations; the highly regulated nature of its business, including government cost-containment initiatives and restrictions on third-party payments for its products; the highly competitive nature of its industry; and other factors set forth in CytoDyn's Annual Report on Form 10-K for the fiscal year ended May 31, 2014 and other reports filed with the U.S. Securities and Exchange Commission.

CONTACTS: Investor Relations:
Wolfe Axelrod Weinberger Associates, LLC
Contact: Robert Schatz, Managing Director
Office: 212-370-4500
E-mail: Rob@wolfeaxelrod.com

Media:
Dr. Nader Pourhassan
Office: 360-980-8524
E-mail: npourhassan@cytodyn.com

Source: CytoDyn