

October 13, 2014



# CytoDyn Announces 100% Success With PRO 140 in Four-Week Monotherapy Clinical Trial

## CytoDyn has requested an "end of Phase 2b meeting" with FDA to discuss Phase 3 plans

VANCOUVER, Washington, Oct. 13, 2014 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTCQB:CYDY), a biotechnology company focused on the development of new therapies for combating infection with human immunodeficiency virus (HIV), today announced the continuation of strong positive results for four weeks of monotherapy with its monoclonal antibody, PRO 140, in patients with HIV-1, who are currently participating in the Company's Phase 2b treatment substitution trial. Management will hold an investment community conference call on October 14, 2014, at 1:00 p.m. PT to discuss the ongoing Phase 2b treatment substitution clinical trial results and the upcoming "end of Phase 2b meeting" with the FDA.

This Phase 2b clinical study was designed to investigate the potential of allowing patients to enjoy treatment interruption from their current HAART regimen concurrent with a monotherapy consisting of weekly injections of PRO 140.

The results from the treatment substitution trial to date have demonstrated 100% success in suppressing the viral load among patients who had weekly injections of PRO 140 for 4 weeks of monotherapy (success defined as zero virologic failures). The Company is requesting FDA clearance to conduct a larger similar Phase 3 licensing trial to demonstrate further the efficacy of PRO 140 for 4 weeks of monotherapy with PRO 140.

The complete trial results to date from all 40 patients (including the first and second cohorts) are:

- As of October 13, 2014, there were zero virologic failures among 21 patients who have reached 4 weeks of monotherapy.
- As of October 13, 2014, 36 patients out of 40 have received at least the first injection of PRO 140.

Comparing these results with previous studies used as historical controls supports the current study's successful outcome. In a 37 patient trial of treatment interruption from HAART, approximately 50% of patients experienced viral load breakout before 4 weeks and approximately 100% showed viral load breakout at eight weeks. In another similar study, results indicated that 10 of 12 patients experienced viral load breakout after just 2 weeks of treatment interruption from HAART.

Dr. Nader Pourhassan, President and CEO, commented: "We believe this is a very strong indication that PRO 140 is effective to allow 4 weeks of drug holiday with weekly injections. PRO 140's safety has been well documented in previous studies, as well as our current study. Moreover, PRO 140's 100% efficacy rate for 4 weeks of treatment substitution provided our technical team with the confidence to recommend that we seek FDA approval for a patient care program of 4 weeks of drug holiday with weekly injections of PRO 140. We are very encouraged with our progress in 2014 and firmly believe the Company is well positioned to make a significant contribution to current treatments of HIV patients."

### **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 humanized monoclonal antibody directed against CCR5, a molecular portal that HIV uses to enter cells.

PRO 140 has been the subject of four Phase 1/1b and two Phase 2a clinical trials, each of which demonstrated its ability to significantly reduce HIV viral load in human test subjects, and has also 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.

### **About CytoDyn**

CytoDyn is a biotechnology company focused on developing subcutaneously delivered humanized cell-specific monoclonal antibodies (mAbs) as entry inhibitors for the treatment and prevention of Human Immunodeficiency Virus (HIV). The Company has one of the leading mAbs under development for HIV infection, PRO 140, which is a Late Stage 2 humanized mAb with demonstrated antiviral activity in man. PRO 140 blocks the HIV co-receptor CCR5 and clinical trial results thus far indicate that it does not affect the normal function of the cell. Results from Phase 1/1b and Phase 2a human clinical trials have shown that PRO 140 can significantly reduce viral burden in people infected with HIV. 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](http://www.cytodyn.com).

### **Forward-Looking Statements**

This press release includes forward-looking statements and forward-looking information within the meaning of United States securities laws. 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.

CONTACT: Investor Relations  
Porter, LeVay & Rose, Inc.  
Michael J. Porter, President  
Office: (212) 546-4700  
E-mail: [mike@plrinvest.com](mailto:mike@plrinvest.com)

Source: CytoDyn Inc.