July 31, 2014

CytoDyn Announces Positive Interim Results From Its Treatment Substitution Study in Patients With HIV

Half of the Patients (Six) Have Experienced 8 Weeks of Successful Drug Holiday on PRO 140 Monotherapy

VANCOUVER, Wash., July 31, 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 positive interim results from its Phase 2b treatment substitution study. The Company will hold an investment community conference call on August 4, 2014, at 9:00 a.m. PT to discuss the trial's protocol, clinical results, and anticipated path forward, as well as to address questions from the call's participants.

This Phase 2b study was designed to investigate the potential for weekly injections of PRO 140, a fully humanized monoclonal antibody, to substitute for a patient's current drug regimen to allow a drug holiday.

The study is to enroll 40 patients in two cohorts, the first with 12 patients followed by a second cohort of 28 patients based on initial safety and efficacy data. All potential study patients are screened and for entry must be HIV positive with the type of virus, 'R5', that uses the coreceptor CCR5 for cell entry and infection. Patients that have a strain of HIV, 'X4', that uses the other coreceptor, CXCR4, are excluded as PRO 140 is not effective in those patients. Dr. Nader Pourhassan, President and CEO, commented, "Currently, there are over 30 drugs approved for HIV/AIDS treatment, but all are believed to have common problems such as drug resistance, side effects with long-term morbidities and a requirement for daily, life-long adherence. We are encouraged by the possibility that PRO 140 may offer these patients the potential to take a sustained drug holiday from their daily regimen of drugs and to improve overall patient health."

The study was initiated on May 13, 2014 and the 12th patient received an initial injection on June 5, 2014. Each patient continued the normal drug regimen plus PRO 140 for the first week, which was then followed by up to 12 weeks of PRO 140 monotherapy. The clinical trial required oversight by an independent Data Safety Monitoring Board ("DSMB") to ensure patient safety and to assess efficacy. The DSMB operates in conformance with the FDA guidelines for its independence, management and oversight. The interim clinical trial results are summarized to date as follows:

- The DSMB met on June 27, 2014 to review the data from the first cohort of 12 patients and noted no adverse reactions or side effects after three weeks of treatment. The

DSMB unanimously recommended that the Company proceed to enroll the next 28-patient cohort to complete the 40-patient study. The DSMB will review the safety and efficacy of the study for the second time on August 13, 2014.

- After four weeks of PRO 140 monotherapy, no patient experienced virologic failure.
- Half the patients maintained suppressed viral loads after 8 weeks of monotherapy.
- Five patients, however, experienced virologic failures. The first of these 'failures' was documented to be a patient qualification screen failure rather than a drug failure. The Company believes that this is a likely cause in the other failures.
    - Virologic failures occurred as follows: three patients failed after 5 weeks of monotherapy, one failed after 6 weeks of monotherapy and one patient failure occurred after 7 weeks of monotherapy.

One inclusion criterion for this study required each patient to have an undetectable viral load for the 12 months prior to enrollment. As only HIV patients who have R5 virus exclusively can benefit from PRO 140, each patient is required to take a DNA Trofile test prior to enrollment in the study. However, this test is only about 50% accurate in patients with an undetectable viral load. Therefore, the Company expected to observe a number of viral rebounds due to inaccurate trofile screening as observed thus far. Of the five patients who demonstrated a rebound in their viral load, one patient has been retested and the test results concluded the patient had a "Dual/Mixed Tropic" HIV-1 virus and should have been excluded from the study. The other four patients have been retested for the qualifying R5 exclusive virus and results are expected shortly. CytoDyn is currently investigating the possibility of developing a more accurate screening test for R5 exclusive virus among patients with undetectable virus.

Dr. Pourhassan added, "Based on the first cohort of patients, our treatment substitution study has yielded the following results: first, the DSMB recommended the enrollment of the second patient cohort based on safety and efficacy indications after three weeks of PRO 140 therapy; second, none of the patients demonstrated viral load failures during the first four weeks of monotherapy; and third, half of the patients did not demonstrate a viral load failure during eight weeks of monotherapy. We believe PRO 140 may prove to be a potential new therapy for HIV patients who need to cycle off conventional treatment regimens."

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.

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.

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Source: CytoDyn, Inc.