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CytoDyn Initiates Phase 3 Monotherapy Trial for HIV Patients

Topline Report for Phase 2b, Along With Phase 3 Monotherapy Protocol Submitted to FDA

VANCOUVER, Wash., Feb. 23, 2016 (GLOBE NEWSWIRE) -- **CytoDyn Inc.** (OTC.QB:CYDY), a biotechnology company focused on the development of new antibody therapies for combating human immunodeficiency virus (HIV) infection, today announced that it submitted a Phase 3 protocol for a monotherapy trial, along with the Topline Report for its Phase 2b monotherapy trial to the U.S. Food and Drug Administration (FDA). This protocol submission was made under the open investigational new drug application (IND) as a monotherapy treatment for HIV and, accordingly, CytoDyn will be permitted to initiate this trial, subject to any comments from the FDA, which will be incorporated into the trial protocol. CytoDyn also expects to sign a new contract with Amarex Clinical Research, its principal CRO, to conduct this study. As previously announced, CytoDyn is currently conducting a pivotal Phase 3 trial for a HIV indication with PRO 140 as an adjunct therapy with the current standard of care for HIV, known as HAART (Highly Active Anti-Retroviral Therapy), and recently initiated a Phase 2 trial for treatment of Graft versus Host Disease (GvHD).

The 300-patient Phase 3 monotherapy trial seeks to provide patients with a treatment option that would enable the use of a long-acting, infrequently administered monotherapy for the chronic suppression of CCR5-tropic HIV-1 infection. The study is designed to test the strategy of offering a carefully selected patient population on suppressive antiretroviral therapy the option of substituting PRO 140 for their oral drug regimen and remaining on PRO 140 for up to 48 weeks contingent on ongoing viral suppression.

CytoDyn's Phase 2b treatment substitution study with PRO 140 was completed in January 2015. As of today, eleven patients have continued with this monotherapy Phase 2b in an extension trial. A majority of these patients have been participating in this trial for nearly 17 months, with two patients approaching 19 months of complete viral load suppression.

The Topline Report contains the summary of the data from the recently concluded Phase 2b PRO 140_CD01 study and ongoing Phase 2b PRO 140 extension study. The CD01 study was designed to evaluate the efficacy, safety and tolerability of PRO 140 monotherapy for the maintenance of viral suppression in 40 subjects who were stable on effective combination antiretroviral therapy. Subjects were shifted from daily oral antiretroviral therapy to PRO 140 monotherapy (with a weekly subcutaneous injection) for up to 12 weeks under the CD01 study. Those subjects who maintained viral suppression for 12 weeks were allowed to continue PRO 140 monotherapy for an additional 60 weeks under the CD01-extension study.

Dr. Nader Pourhassan, President and CEO, commented: “We are pleased to have continuously progressed forward with our promising data from our previous monotherapy trial to the current extension arm of our monotherapy trial. The Phase 3 monotherapy trial is a crucial milestone for us and we believe that we are now on the last step of advancing this valuable product to the market, upon approval. We estimate that the market opportunity for monotherapy is well over a billion dollars.”

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. CytoDyn 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 and to pursue non-HIV indications where CCR5 and its ligand CCL5 may be involved. For more information on CytoDyn, 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 CytoDyn’s Phase 3 and other current and proposed trials and studies and their results and 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, 2015 and other reports filed with the U.S. Securities and Exchange Commission.

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