CytoDyn Signs Agreement with Amarex Clinical Research LLC to Prepare Two Phase 2b Clinical Trial Protocols to Explore Two Additional Therapeutic Indications for PRO 140

Company plans to expand clinical development program for lead product candidate

VANCOUVER, Wash.-- CytoDyn Inc. (OTCQB: CYDY), a biotechnology company focused on the development of new therapies for combating infection with immune deficiency viruses, announced today that the Company plans to expand its clinical development program for PRO 140 and signed an agreement with Amarex Clinical Research LLC to prepare two Phase 2b clinical trial protocols to explore two additional therapeutic indications for its lead product candidate. One of the new protocols is expected to be completed in the first quarter of 2014 and the second protocol early in the second quarter of 2014. After submission of the Phase 2b clinical trial protocols to the U.S. Food and Drug Administration (FDA), the Company and Amarex will work with the FDA to obtain approval to commence the trials.

Amarex is a global Contract Research Organization (CRO) that provides complete clinical product development services to pharmaceutical companies to achieve FDA approval for their new medical products. Amarex has expertise in product development plan creation, product safety and efficacy testing, and applications to the FDA for marketing approval of new or improved medical products.

Nader Pourhassan, Ph.D., CytoDyn’s President and Chief Executive Officer, stated, “Since we acquired PRO 140, we had concentrated our efforts on advancing the development programs that had already been put in place. More recently, in collaboration with our Scientific Advisory Board, David Feigal, M.D., our Chief Medical Officer, and his team have been working to identify the best clinical development pathways for PRO 140. We believe we have identified two new indications that may lead to an opportunity for PRO 140 to address areas of significant unmet need for physicians and patients and, ultimately, generate significant shareholder value.”

Dr. Feigal commented, “I am excited we have the opportunity to expand the clinical development program for PRO 140 and very pleased to be working closely with Amarex in developing and finalizing protocols for two new indications. We have specifically chosen to work with Amarex to prepare and finalize these important clinical trial protocols for CytoDyn as we firmly believe their expertise and proven track record with the FDA is perfectly aligned with our clinical development strategy and priorities for PRO 140.”
Kazem Kazempour, Ph.D., Amarex’s President and Chief Executive Officer, said, “Amarex is very pleased to have the opportunity to support CytoDyn in the development of PRO 140. We believe our extensive experience in clinical trial management, HIV-related research, and parallel processing of trial services, will enable CytoDyn to complete these trials as quickly as possible, and with the greatest chance of success.”

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 PRO 140’s 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 while not being a drug, 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 and other reports filed with the U.S. Securities and Exchange Commission.

**Investors and Media**

Jenene Thomas Communications, LLC
Jenene Thomas, 908-938-1475
Investor Relations and Corporate Communications Advisor
jthomas@cytodyn.com

Source: CytoDyn Inc.