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CytoDyn to Present New Data from Study of Investigational HIV Therapy Leronlimab (PRO 140), a Long-Acting, Single-Agent Maintenance Therapy at CROI 2019

VANCOUVER, Washington, Feb. 27, 2019 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY**), a late stage biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, today announced that data from its study of leronlimab (PRO 140) is scheduled to be presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2019) on March 7, 2019. Leronlimab is a once weekly, subcutaneous injection that blocks HIV-1 from entering and infecting human cells by binding to the CCR5 receptor with high affinity. The abstract and poster will be available at www.cytodyn.com at approximately the same time as the poster presentation.

The annual Conference on Retroviruses and Opportunistic Infections (CROI) brings together top basic, translational, and clinical researchers from around the world to share the latest studies, important developments, and best research methods in the ongoing battle against HIV/AIDS and related infectious diseases. CROI 2019 will be held from March 4 to March 7, 2019, at the Washington State Convention Center in Seattle, Washington.

CytoDyn's Poster at CROI 2019:
Poster # 486: PRO 140 (leronlimab) SC: Long-Acting, Single-Agent Maintenance Therapy for HIV-1 Infection

- *Presenters: Drs. Kush Dhody* and *Nader Pourhassan*
- *Date: Thursday, March 7, 2:30pm-4:00pm, Poster Hall – 4EF*

"CytoDyn's commitment to providing groundbreaking therapeutic advances for those in need has never been stronger. We remain highly encouraged by the continued clinical and regulatory progress to bring the next generation HIV treatment to patients," stated Dr. Nader Pourhassan, President, CEO and Director of CytoDyn.

Dr. Pourhassan concluded, "CytoDyn is in the process of completing a Biologics License Application (BLA) with the FDA for leronlimab (PRO 140) as a combination therapy with HAART for HIV-infected patients. Then, subject to approval by the FDA as a combination therapy, CytoDyn plans to file for a label expansion for leronlimab (PRO 140) as a monotherapy, providing the company can achieve positive results from a proposed Phase 3 pivotal trial with leronlimab (PRO 140) as a monotherapy."

About Leronlimab (PRO 140)
Leronlimab (PRO 140) is an investigational humanized IgG4 monoclonal antibody that

blocks CCR5, a cellular receptor that plays multiple roles with implications in HIV infection, tumor metastasis, and immune signaling.

In the setting of HIV/AIDS, leronlimab belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. At the same time, leronlimab does not appear to interfere with the normal function of CCR5 in mediating immune responses. Leronlimab has been the subject of seven clinical trials, each of which demonstrated that leronlimab can significantly reduce or control HIV viral load in human test subjects. Leronlimab has been designated a “fast track” product by the FDA. The leronlimab antibody appears to be a powerful antiviral agent leading to potentially fewer side effects and less frequent dosing requirements compared with daily drug therapies currently in use.

In the setting of cancer, research has shown that CCR5 likely plays a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in several cancers. Moreover, research has shown that drugs that block CCR5 can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with leronlimab in the cancer setting and plans to initiate Phase 2 human clinical trials when appropriate.

The CCR5 receptor also appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be crucial for the development of acute graft-versus-host disease (GvHD) and other inflammatory conditions. Clinical studies by others further support the concept that blocking CCR5 using a chemical inhibitor can reduce the clinical impact of acute GvHD without significantly affecting the engraftment of transplanted bone marrow stem cells. CytoDyn is currently conducting a Phase 2 clinical study with leronlimab to further support the concept that the CCR5 receptor on engrafted cells is critical for the development of acute GvHD and that blocking this receptor from recognizing certain immune signaling molecules is a viable approach to mitigating acute GvHD. The FDA has granted orphan drug designation to leronlimab for the prevention of graft-versus-host disease (GvHD).

About CytoDyn

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab (PRO 140), a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a key role in the ability of HIV to enter and infect healthy T-cells. The CCR5 receptor is also appears to be implicated in tumor metastasis and in immune-mediated illnesses such as graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biological License Application (BLA) in 2019 for that indication. CytoDyn is also conducting a Phase 3 investigative trial with leronlimab as a once-weekly monotherapy for HIV-infected patients, and plans to initiate a registration-directed study of leronlimab monotherapy indication, which if successful, could support a label extension. Clinical results to date from multiple trials have shown that leronlimab can significantly reduce viral burden in people infected with HIV with no reported drug-related serious adverse events (SAEs). Moreover, results from a Phase 2b clinical trial demonstrated that leronlimab monotherapy can prevent viral escape in HIV-infected

patients, with some patients on leronlimab monotherapy remaining virally suppressed for more than four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and has received clearance to initiate a clinical trial with leronlimab in metastatic triple-negative breast cancer. More information is at www.cytodyn.com.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the sufficiency of the Company's cash position, (ii) the Company's ability to raise additional capital to fund its operations, (iii) the Company's ability to meet its debt obligations, if any, (iv) the Company's ability to enter into partnership or licensing arrangements with third parties, (v) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion, (vi) the Company's ability to achieve approval of a marketable product, (vii) the design, implementation and conduct of the Company's clinical trials, (viii) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results, (ix) the market for, and marketability of, any product that is approved, (x) the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products, (xi) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, (xii) general economic and business conditions, (xiii) changes in foreign, political, and social conditions, and (xiv) various other matters, many of which are beyond the Company's control. The Company urges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in any subsequent Form 10-Q or Form 8-K, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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