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CytoDyn Treats First Patient with Leronlimab in Phase 2 Trial for GvHD under Modified Trial Protocol

VANCOUVER, Washington, March 04, 2020 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today the treatment of the first patient in its Phase 2 clinical trial for graft-versus-host disease (GvHD) under the modified trial protocol.

The modified protocol now includes reduced intensity conditioning (RIC) patients and an open-label design under which all enrollees receive leronlimab. The modified protocol also provides for a 50% increase in the dose of leronlimab to more closely mimic preclinical dosing. The next review of data by the independent data monitoring committee (iDMC) will occur following enrollment of 10 patients under the amended protocol after each patient has been dosed for 30 days.

Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn, added, "GvHD is a life-threatening complication following bone marrow transplantation in patients with leukemia who have compromised immune systems due to treatment with aggressive cancer therapies. We selected GvHD as one of our immunology indications for leronlimab, as it targets and masks the CCR5 receptor on T cells. This receptor on T cells is an important mediator of inflammatory diseases including GvHD, especially in organ damage that is the most frequent cause of death in these patients." Dr. Pourhassan concluded that, "Based upon the compelling results in our preclinical studies, we are optimistic about the opportunities for leronlimab to provide a therapy for transplant patients to mitigate GvHD."

The Company's preclinical study by Denis R. Burger, Ph.D., CytoDyn's former Chief Science Officer, and Daniel Lindner, M.D., Ph.D. of the Department of Translational Hematology and Oncology Research, The Cleveland Clinic, was published online in the peer-reviewed journal *Biology of Blood and Marrow Transplantation.*

The Company previously reported that the U.S. Food and Drug Administration (FDA) granted orphan drug designation to leronlimab (PRO 140) for the prevention of GvHD. Orphan drug designation is granted to development-stage drugs that have shown promise in addressing serious medical needs for patients living with rare conditions. This designation provides CytoDyn with various incentives and benefits including seven years of U.S. market exclusivity for leronlimab (PRO 140) in GvHD, subject to FDA approval for use in this indication.

About Graft-versus-Host Disease (GvHD)
Graft-versus-host disease is a risk when patients receive the transplant of bone marrow

stem cells donated from another person. GvHD occurs when the donor's immune cells attack the patient's normal cells. GvHD can be acute or chronic. Its severity depends on the differences in tissue type between patient and donor. The older the patient, the more frequent and serious the reaction may be. Acute GvHD can occur soon after the transplanted cells begin to appear in the recipient and can range from mild, moderate or severe, and be life-threatening if its effects are not controlled. Certain approved drugs exist that can help prevent or lessen GvHD. However, GvHD does not always respond to these treatments, and it can still result in fatal outcomes. Furthermore, many deaths related to GvHD occur because of infections that develop in patients whose immune systems are suppressed by such drugs.

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) has granted a "Fast Track" designation to CytoDyn for two potential indications of leronlimab for deadly diseases. The first as a combination therapy with HAART for HIV-infected patients and the second is for metastatic triple-negative breast cancer. Leronlimab is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that is important in HIV infection, tumor metastases, and other diseases including NASH. Leronlimab has successfully completed nine clinical trials in over 800 people, including meeting its primary endpoints in a pivotal Phase 3 trial (leronlimab in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

In the setting of HIV/AIDS, leronlimab is a viral-entry inhibitor; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Leronlimab has been the subject of nine clinical trials, each of which demonstrated that leronlimab can significantly reduce or control HIV viral load in humans. 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 plays an important role in tumor invasion and metastasis. Increased CCR5 expression is an indicator of disease status in several cancers. Published studies have shown that blocking CCR5 can reduce tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. Leronlimab reduced human breast cancer metastasis by more than 98% in a murine xenograft model. CytoDyn is therefore conducting a Phase 1b/2 human clinical trial in metastatic triple-negative breast cancer and was granted Fast Track designation in May 2019. Additional research is being conducted with leronlimab in the setting of cancer and NASH with plans to conduct additional clinical studies when appropriate.

The CCR5 receptor appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be important in the development of acute 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 GvHD.

About CytoDyn
CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab, 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 also appears to be implicated in tumor metastasis and in immune-mediated illnesses, such as GvHD and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab in combination with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biologics License Application (BLA) in the first quarter of 2020 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 five years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and a Phase 1b/2 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.

CYTODYN CONTACTS
Investors:
Dave Gentry, CEO
RedChip Companies
Office: 1.800.RED.CHIP (733.2447)
Cell: 407.491.4498
dave@redchip.com

Source: CytoDyn Inc.