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# CytoDyn Announces Stunning Results from Clinical Trials Evaluating mTNBC and MBC with Leronlimab and will Request an Emergency Type C Meeting with FDA to Enroll 50 Awaiting Patients with a Serious Solid Tumor Cancer Condition

## Third patient data supports leronlimab (PRO 140) as a potential treatment option for metastatic triple-negative breast cancer (mTNBC) and metastatic breast cancer (MBC). Patient CTC dropped to zero after 2 weeks of leronlimab treatment, same as the first patient on leronlimab

VANCOUVER, Washington, Jan. 31, 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 very strong data from patients in its clinical trials with metastatic triple-negative breast cancer (mTNBC) and metastatic breast cancer (MBC).

New data from the first patient enrolled in the Company's mTNBC Phase 1b/2 trial showed no detectable levels of circulating tumor cells (CTC) with leronlimab in combination with carboplatin at 16 weeks of treatment. In addition, this patient experienced significant reductions in epithelial-mesenchymal transition (EMT) cells dropping to zero after five weeks with treatment and currently reports zero EMT. New data from the second patient enrolled in the Company's mTNBC Phase 1b/2 trial showed no detectable levels of CTC with leronlimab in combination with carboplatin after two weeks of treatment. This patient also showed a 70% reduction in EMT cells after just two weeks of treatment. Initial data from the third patient in the mTNBC trial indicated the CTC dropped to zero after two weeks of treatment with leronlimab.

"Remarkably, the new patient enrolled in the clinical trial showed a significant drop in CTC and a reduction of EMT cells, the putative metastatic cells from 7 per 4mL of blood to two cells in just two weeks of treatment with leronlimab in combination with carboplatin," said Bruce Patterson, M.D., chief executive officer and founder of IncellDx, a diagnostic partner and an advisor to CytoDyn. "The rapid response to the treatment in a pattern that is identical to previous patients is equally as remarkable and supports a predictable method of action for this drug. Additionally, no adverse effects were observed in the clinical trials, further supporting leronlimab's potential safety profile."

New findings from the patient enrolled through an emergency investigational new drug (IND) with stage 4 HER2+ MBC that has metastasized to the liver, lung and brain, demonstrate no new metastasis in the brain after treatment with leronlimab as the only product for the metastasis to her brain. Prior to enrolling in the trial, the patient had 18 identifiable tumor spots in the brain. Today, following two months of weekly 700 mg doses of leronlimab, there are only three identifiable lesions, as seen in an MRI. This patient's radiologist cancelled the suggested new round of radiation due to results that he believes is due only to leronlimab.

"We are excited to see this continuous spectacular data that further supports leronlimab as a potential game-changing treatment for patients living with cancer," said Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn. "As a company, our hope is to bring suffering patients safe and effective treatment options. Today, we have heard from over 50 individuals who are waiting to be treated with leronlimab and our regulatory team is reaching out to the FDA to organize an emergency Type C meeting to discuss the data evidenced in our clinical trials. This is an extremely exciting time for CytoDyn, as we continue to demonstrate our commitment to patients through the development of leronlimab. All patients' oncologists and CytoDyn's thought leaders will convene an urgent meeting to discuss strategy in order to bring immediate awareness of leronlimab's potential for all patients with solid tumors, which could represent approximately 22 different forms of cancer."

**About Triple-Negative Breast Cancer**

Triple-negative breast cancer (TNBC) is a type of breast cancer characterized by the absence of the three most common types of receptors in the cancer tumor known to fuel most breast cancer growth–estrogen receptors (ER), progesterone receptors (PR) and the hormone epidermal growth factor receptor 2 (HER-2) gene.[1] TNBC cancer occurs in about 10 to 20 percent of diagnosed breast cancers and can be more aggressive and more likely to spread and recur.[2,3] Since the triple-negative tumor cells lack these receptors, common treatments for breast cancer such as hormone therapy and drugs that target estrogen, progesterone, and HER-2 are ineffective.[4] Currently, there are no targeted therapies approved to treat triple-negative breast cancer.[5]

**About Leronlimab (PRO 140)**

The U.S. Food and Drug Administration (FDA) have 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 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 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 anti-retroviral 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 (PRO 140) 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 (PRO 140) 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.

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Source: CytoDyn Inc.