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Impressive Results Continue from CytoDyn's Clinical Trials Evaluating Two Patients with Leronlimab, One in mTNBC and One in MBC

First patient with metastatic triple-negative breast cancer (mTNBC) continues to show no detectable circulating tumor cells (CTC) or putative metastatic tumor cells after 15 weeks of treatment with leronlimab in combination with carboplatin

Second patient with stage 4 HER2+ metastatic breast cancer (MBC) shows 50 percent shrinkage in the primary tumor and no new signs of metastasis in the brain after treatment with leronlimab as a monotherapy

VANCOUVER, Washington, Jan. 22, 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 additional promising results from its clinical trials evaluating leronlimab for the treatment of metastatic triple-negative breast cancer (mTNBC) and metastatic breast cancer (MBC).

New data from the first patient enrolled in the Company's metastatic triple-negative breast (mTNBC) Phase 1b/2 trial continues to show no detectable levels of circulating tumor cells (CTC) or putative metastatic cells in the peripheral blood following 15 weeks of treatment with leronlimab in combination with carboplatin.

The second patient, enrolled through an emergency investigational new drug (IND) with stage 4 HER2+ MBC that has metastasized to the liver, lung and brain, showed a 50 percent shrinkage of the primary tumor and no new metastasis in the brain after treatment with leronlimab as a monotherapy. The patient was previously treated with pertuzumab and trastuzumab for over a year and a half. This patient has been taking leronlimab since November 25, 2019 with one 700 mg dose each week.

"Recent testing of the first patient demonstrated continued absence of CTCs in all blood tubes with only one cancer-associated macrophage like cells (CAMLs) in one of two tubes. In the second patient, the follow up brain scan conducted on January 17, 2020, showed that the largest brain lesion had a greater than 4-fold reduction in size," said Bruce Patterson, M.D., chief executive officer and founder of IncellDx, a diagnostic partner and an advisor to CytoDyn. "Other smaller lesions on the second patient's brain have not changed in size and cerebral edema remains at decreased levels since the last imaging studies. Taken together, these results suggest continued response of both primary and metastatic tumors to treatment with leronlimab for both the first and second patient."

Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn, added: “We are thrilled to see these additional data that further support leronlimab as a potential treatment option for patients with mTNBC and MBC. As a Company, we look forward to continuing our work in the oncology space and developing a potentially safe and effective treatment option for patients suffering from this deadly disease.”

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 anti-retroviral 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 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 2019 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 four 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.