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CytoDyn Receives Institutional Review Board Approval to Initiate Phase 2 Basket Trial for 22 Solid Tumor Cancers

Results from mTNBC and MBC studies continues to be positive with the first patient now at almost five months of treatment showing zero CTC, EMT and CAML. Seven patients have been enrolled to date

VANCOUVER, Washington, Feb. 21, 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, reported that it has received Institutional Review Board (IRB) approval to begin its Phase 2 clinical trial for the treatment of approximately 22 different solid tumor cancers, including melanoma, brain-glioblastoma, throat, lung, stomach, colon carcinoma, breast, testicular, ovarian, uterine, pancreas, bladder, among other indications.

Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn, stated, "We currently have more than 70 patients eagerly waiting to participate in this basket trial and expect the first patient injection to take place within approximately ten days. Furthermore, overall enrollment of the trial could be completed in as little as 30 to 60 days, as this is a 30-patient trial."

This basket trial is a 30 patient, CCR5+ Phase 2 study with locally advanced or metastatic solid tumors. Leronlimab will be administered subcutaneously as a weekly dose of 350 mg. Patients participating in this study will be allowed to receive and continue the standard-of-care chemotherapy as determined by the treating physician.

The clinical trial will take place at multiple sites across the U.S., with preliminary results on each patient expected within three to four weeks after the initial treatment with leronlimab. The primary endpoint of the basket trial is progression-free survival.

"Peripheral blood sampling from Patient #1 in the mTNBC trial, who has been on leronlimab for approximately five months, revealed no cancer cells or cancer associated cells (0 CTC, 0 EMT and 0 CAML). In addition, Patient #2, who has been on leronlimab for almost 3 months in the MBC study, with brain metastasis, continues to show in the latest CT scan, stable lesions that are now described as scar-like suggesting repair in the metastatic tumors," added Bruce Patterson, M.D., chief executive officer and founder of IncellDx, a diagnostic partner and an advisor to CytoDyn. "These data are substantiating the relationship between CCR5 and immune cell infiltrates and response which supports the current basket trial."

"Our current basket trial focuses on method of action (MOA) rather than a specific cancer type," continued Dr. Pourhassan. "We are extremely pleased the central IRB provided

approval to proceed with the trial in a matter of weeks. This process can often take two months or more. If leronlimab proves to be as effective in this basket trial, as we have seen in our mTNBC and MBC patients, this opens up a strong potential for CytoDyn to file for another Breakthrough Therapy designation (BTD) for the 22 cancer indications being evaluated in this trial."

About Basket Trials
A basket trial involves a single investigational drug or drug combination that is studied across multiple cancer populations defined by disease stage, histology, number of prior therapies, genetic or other biomarkers, or demographic characteristics. It is usually designed as a single-arm, activity-estimating trial with overall response rate as the primary endpoint. A strong response signal seen in a sub-study may allow for expansion to generate data that could potentially support a marketing approval.[1]

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 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.

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[1] https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-modernizes-clinical-trials-master-protocols-february-26-2019-issue

Source: CytoDyn Inc.