February 6, 2020

CytoDyn Files a Phase 2 Basket Trial with Leronlimab (PRO 140) for Treatment of All Solid Tumor Cancers

VANCOUVER, Washington, Feb. 06, 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 that it has filed a Phase 2 protocol for a basket trial with the U.S. Food and Drug Administration (FDA) under its cancer IND. The Company can immediately initiate enrollment in this 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. The Company expects to receive preliminary results on each patient within 3 to 4 weeks after the initial treatment with leronlimab. The Company will continue to enroll patients in its metastatic breast cancer trials.

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

Bruce Patterson, M.D., chief executive officer and founder of IncellDx, a diagnostic partner and an advisor to CytoDyn commented, "The results so far in breast cancer patients have remarkably demonstrated the shrinking of primary tumors, the shrinking or elimination of metastatic lesions, and the reduction of CTCs to zero which has remained stable over weeks. In other studies, we have seen CTC levels in this cancer >5 and some as high as 20 per 4 mL of blood. Further, these data help define the relationship between CCR5 on immune cell infiltrates and response as we analyze these responding patients."

"If leronlimab proves to be as effective in this basket trial as we have seen in the first 4 patients in our MBC trials, we believe we will be able to file for another breakthrough therapy designation (BTD) for the multiple cancer indications evaluated in this basket trial, which could cover approximately 22 different forms of cancers," said Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn. "Since we started our cancer trials for mTNBC and compassionate use and expanded access for MBC, we have received requests from patients in the U.S. and overseas. More than 50 patients have requested to use leronlimab and our current basket trial will be able to quickly screen all these patients."

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 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 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.

CONTACTS

Investors:
Dave Gentry, CEO

RedChip Companies
Office: 1.800.RED.CHIP (733.2447)
Cell: 407.491.4498
dave@redchip.com

[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.