FDA Grants CytoDyn Fast Track Designation for Leronlimab (PRO 140) in metastatic Triple-Negative Breast Cancer, an Unmet Medical Need

VANCOUVER, Washington, May 07, 2019 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB: CYDY), ("CytoDyn" or the "Company"), a late stage biotechnology company developing leronlimab (PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, today announced that the U.S. Food and Drug Administration ("FDA") has granted Fast Track Designation to leronlimab (PRO140) for use in combination with carboplatin for the treatment of patients with CCR5-positive metastatic triple-negative breast cancer (mTNBC). Injection of the first patient in mTNBC is anticipated to be imminent. Clinical trial sites include Quest Clinical Research in San Francisco, along with four additional trial sites, which are in the process of initiating patient enrollment, including: Northwestern University Medical School, Methodist Houston, Vanderbilt University and Sidney Kimmel Cancer Center.

“This is an important acknowledgement of the potentially paradigm-shifting therapy option in metastatic triple-negative breast cancer,” stated Dr. Richard Pestell, M.D., Ph.D, Vice Chairman and Chief Medical Officer of CytoDyn. “Currently, there are no enduring treatment options for mTNBC patients and, we thank the FDA for recognizing the potential of leronlimab for mTNBC patients,” continued Dr. Pestell. “We remain highly encouraged by the potential of leronlimab (PRO 140) as a pipeline of opportunities within a single drug franchise,” stated Dr. Nader Pourhassan, Ph.D, President, CEO and director. “Our BLA for leronlimab as a combination therapy in HIV remains on track for completion in the third quarter of 2019, or sooner, and potential FDA approval before end of the first quarter of 2020, or sooner,” continued Dr. Pourhassan. “Plus, with the potential label extension as a monotherapy in HIV following the potential approval as a combination therapy, along with our Phase 2 development of leronlimab for GvHD and several other preclinical studies for metastatic solid tumors, the path to significant and enduring shareholder returns continues to take shape,” concluded Dr. Pourhassan.

About U.S. FDA Fast Track Designation (FTD)

“Fast Track” is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. Determining whether a condition is serious is a matter of judgement, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. A drug that receives Fast Track designation is eligible for some or all of the following:

- More frequent meetings with the FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval;
- More frequent written communications from the FDA about such things as the design of the proposed clinical trials and use of biomarkers;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met;
- Rolling Review, which means that a drug company can submit completed sections of its Biologics License Application (BLA) for review by the FDA, rather than waiting until every section is completed before the application can be reviewed.

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) has granted a “Fast Track” designation to leronlimab (PRO 140) as a combination therapy with HAART for HIV-infected patients. Leronlimab (PRO 140) is an investigational humanized IgG4 mAb that blocks CCR5, a cellular receptor that appears to play multiple roles with implications in HIV infection, tumor metastases and immune signaling. Leronlimab (PRO 140) has successfully completed nine Phase 1/2/3 clinical trials in over 700 people, including a successful pivotal Phase 3 trial in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients.

In the setting of HIV/AIDS, leronlimab (PRO 140) belongs to a new class of therapeutics called viral-entry inhibitors; it masks CCR5, thus protecting healthy T cells from viral infection by blocking the predominant HIV (R5) subtype
from entering those cells. Leronlimab (PRO 140) 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 (PRO 140) 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 likely plays a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in several cancers. Moreover, research has shown that drugs that block CCR5 can block tumor metastases in laboratory and animal models of aggressive breast and prostate cancer. CytoDyn is conducting additional research with leronlimab (PRO 140) in the cancer setting and plans to initiate additional Phase 2 human clinical trials, in addition to triple-negative breast cancer, when appropriate.

The CCR5 receptor also appears to play a central role in modulating immune cell trafficking to sites of inflammation and may be crucial for 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 (PRO 140) 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 (PRO 140) for the prevention of graft-versus-host disease (GvHD).

**About CytoDyn**

CytoDyn is a biotechnology company developing innovative treatments for multiple therapeutic indications based on leronlimab (PRO 140), 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 graft-vs-host disease (GvHD) and NASH. CytoDyn has successfully completed a Phase 3 pivotal trial with leronlimab (PRO 140) in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. CytoDyn plans to seek FDA approval for leronlimab (PRO 140) 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 (PRO 140) 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 (PRO 140) for the prevention of GvHD and has received clearance to initiate a clinical trial with leronlimab (PRO 140) in metastatic triple-negative breast cancer. More information is at [www.cytodyn.com](http://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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