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Leronlimab (PRO 140) reduces by more than 98% human breast cancer metastasis in mouse xenografts for over 6 weeks

Based on strong results in its pre-clinical animal study, CytoDyn files for Orphan Drug Designation for Triple-Negative Breast Cancer

VANCOUVER, Washington, Feb. 20, 2019 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTC.QB: CYDY), a biotechnology company developing a novel humanized CCR5 monoclonal antibody for multiple therapeutic indications, announces that it was able to reduce by more than 98% the incidence of human breast cancer metastasis in a mouse xenograft model for cancer through six weeks with leronlimab (PRO 140). Based on these results, CytoDyn announced yesterday its plans for the expansion of pre-clinical animal studies into eight cancer indications, driven in part on prior research by Dr. Pestell suggesting that CCR5 inhibition may disrupt signaling and ultimately the spread of CCR5+ Circulating Tumor Cells (CTC's).

In Dr. Pestell's research laboratory, pre-clinical studies were conducted on mice using Pfizer's HIV drug maraviroc in breast and prostate cancer. Results were most encouraging using these CCR5 inhibitors, which ultimately led Dr. Pestell to design experiments applying leronlimab (PRO 140) to metastatic mouse models. The results of this pre-clinical study using leronlimab (PRO 140) in mice showed a reduction in breast cancer metastasis of more than 98% over the six-week period of the study. The mouse xenograft model is designed to mimic human breast cancer metastasis. With more than 98% reduction in tumor metastasis over a six-week period, in the mouse model, the company is optimistic about the potential for human development. The temporal equivalency of the murine 6 weeks study, may be up to 6 years in humans.

"These positive pre-clinical results are very promising, and it gives new hope for future treatment options to cancer victims all over the world. We are working diligently to present an abstract of this data in conference as soon as possible," said Dr. Nader Pourhassan, President and CEO of CytoDyn. "Should CytoDyn's mouse xenograft breast cancer metastasis studies using leronlimab (PRO 140) correlate in humans (as Pfizer's drug maraviroc did in colon cancer, in a trial conducted in Germany (see results on CytoDyn's website (www.cytodyn.com))), this could open new possibilities for treatment options for breast cancer. New treatment options of this kind would be welcome news for late stage cancer patients, who often experience deadly metastasis."

Dr. Pourhassan continued, "We look forward with great anticipation to receiving interim data from our human trial in triple-negative breast cancer (TNBC), which is expected to be available within the next few months. If interim results are positive, we will promptly file for

breakthrough therapy designation.” Dr. Pourhassan continued, “Negotiation of potential licensing opportunities has started on several fronts. We hope to reach a definitive deal regarding a commercialization partnership for HIV and/or GvHD, which would further enhance the trajectory of our company.”

About Leronlimab (PRO 140)

Leronlimab (PRO 140) is a humanized IgG4 monoclonal antibody that blocks CCR5, a cellular receptor that plays multiple roles with implications in HIV infection, tumor metastasis, and immune signaling.

In the setting of HIV/AIDS, leronlimab 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. At the same time, leronlimab does not appear to interfere with the normal function of CCR5 in mediating immune responses. Leronlimab has been the subject of seven clinical trials, each demonstrating efficacy by significantly reducing or controlling HIV viral load in human test subjects. Leronlimab has been designated a “fast track” product by the FDA. 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 a central role in tumor invasion and metastasis and that increased CCR5 expression is an indicator of disease status in several cancers. Moreover, researchers have 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 in the cancer setting and plans to initiate Phase 2 human clinical trials when appropriate.

The CCR5 receptor also plays a central role in modulating immune cell trafficking to sites of inflammation and it is 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 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 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 is also 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 in combination with standard anti-retroviral therapies in HIV-infected treatment-experienced patients. The Company plans to seek FDA approval for leronlimab in combination therapy and plans to complete the filing of a Biological License Application (BLA) in the first half of 2019 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 four years. CytoDyn is also conducting a Phase 2 trial to evaluate leronlimab for the prevention of GvHD and has received clearance to initiate a clinical trial with leronlimab in metastatic triple-negative breast cancer in 2018. 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:

Nader Pourhassan, Ph.D.
President & CEO
(360) 980-8524
npourhassan@cytodyn.com



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