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CytoDyn Signs Letter of Intent for the Joint Development and Licensing of Leronlimab in China with Longen China Group

VANCOUVER, Washington, Feb. 12, 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 the Company signed a nonbinding letter of intent (LOI) for the joint development and licensing of leronlimab in China with Longen China Group ("Longen"). CytoDyn and Longen will begin exploring opportunities for leronlimab for the treatment of the 2019 Novel Coronavirus (2019-nCoV) and cancer.

"We are thrilled to partner with Longen, one of the largest medical service providers in China, to develop leronlimab as a potential treatment for coronavirus and cancer," said Nader Pourhassan, Ph.D., president and chief executive officer of CytoDyn. "By working together and leveraging our expertise, we hope to bring effective and safe treatments to patients suffering from these deadly diseases."

Leronlimab has the potential to enhance the cellular immune response to the 2019-nCoV and could synergize with other retroviral therapies that are currently being used as the potential treatments. In oncology, CytoDyn has previously reported strong clinical data from three patients participating in the Company's Phase 1b/2 trial for the treatment of metastatic triple-negative breast cancer (mTNBC) and from one patient with stage 4 HER2+ MBC that has metastasized to the liver, lung and brain, who was enrolled through an emergency investigational new drug (IND).

Wenbao Bi, chief executive officer of Longen China Group, added, "The biotech and healthcare communities desperately need to identify new and potential treatments to limit the spread of 2019-nCoV as quickly as possible. We support CytoDyn's efforts to explore the potential uses of leronlimab to help patients who are suffering from 2019-nCoV. We also look forward to working with CytoDyn to address indications within oncology."

Bruce Patterson MD, chief executive officer of IncellDx added, "IncellDx's companion diagnostic partnership with Cytodyn has shown that leronlimab can target cells that inhibit the innate and cellular immune responses which are critical in both viral infections and cancer. Our strong relationship with both companies will allow us to quickly initiate trials and to rapidly monitor safety and dosing of leronlimab in the 2019-nCoV epidemic and long term in cancer patients."

About 2019 Novel Coronavirus
The 2019 Novel Coronavirus (2019-nCoV) was identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China.[1] The origin of 2019-nCoV is uncertain and it is unclear how easily the virus spreads.[2] 2019-nCov is thought to be transmitted person to person through respiratory droplets, commonly resulting from coughing sneezing and close personal contact.[3] Coronaviruses are a large family of viruses, some causing illness in people and others that circulate among animals.[4] For confirmed 2019-nCoV infections, symptoms have included fever, cough and shortness of breath.[5] It is believed that symptoms of 2019-nCoV may appear in as few as two days or as long as 14 days prior to exposure, and that symptoms in patients have ranged from non-existent to severe and fatal.[6] There are currently no known anti-viral treatments effective at suppressing 2019-nCoV.[7]

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.[8] 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.[9,10] 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.[11]

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.

About Longen Group (Genben Biotechnology)
Long Jian International (Hong Kong) Group relies on China's future health industry blue ocean, based on the national health vent field, The Group has the industry's top technology research and development team, marketing planning team and advanced business management concept. With a number of well-known research institutions at home and abroad, with a number of invention patents and independent intellectual property rights, is a collection of scientific research, production, marketing, service in one of the high-tech enterprise group. The Group's Fundamental Biotechnology (Shanghai) Co., Ltd. is a technology-intensive, innovative enterprise based on modern medical and life sciences. At present, we have a GMP cell R&D and preparation center in line with international standards in China. At the same time with a number of well-known domestic third-class first-class hospitals to carry out clinical research and transformation.

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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