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CytoDyn Strengthens Management Team with Key Additions in Business Development and Quality Regulatory Compliance as it Advances Commercialization Plan for Leronlimab

VANCOUVER, Washington, May 14, 2019 (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, today announced the hiring of Brendan Rae, Ph.D., J.D., as Senior Vice President of Business Development and George Bitar as Executive Director - Head of Quality. The addition of these senior positions aligns with CytoDyn's pursuit of strategic partnership agreements and efforts to attain its first FDA approval.

Dr. Rae will lead CytoDyn's business development initiatives, including all potential partnering and licensing opportunities for leronlimab. Dr. Rae is an accomplished licensing and business development executive with a proven track record of deal-making. Dr. Rae comes to CytoDyn from Serina Therapeutics where he was Chief Business Officer, responsible for partnering, out licensing and overall company strategy. Previously, Dr. Rae was the Executive Director of NPS Pharmaceuticals and Head of GI and Endocrinology Business Development until the acquisition by Shire Pharmaceuticals for $5.2 billion in 2015. Prior to NPS, Dr. Rae held the role of Chief Business Officer at Arrowhead Research and Vivaldi Biosciences, as well as senior leadership roles at VIA Pharmaceuticals, Purdue Pharma and Hoffman-La Roche. Prior to entering the biopharmaceutical industry, Dr. Rae was an attorney specializing in biopharmaceutical intellectual property law and, earlier in his career was a research scientist focusing on metastasis and the molecular basis of cellular transformation. Dr. Rae holds a Juris Doctor degree from Seton Hall Law School and a Ph.D. in Virology from Glasgow University (Scotland) and completed a Postdoctoral Fellowship at the Roche Institute of Molecular Biology.

Mr. Bitar will be responsible for overseeing all facets of the company's Quality Systems, Quality Assurance, and Compliance Operations to ensure that product is manufactured consistently to meet all FDA standards. As CytoDyn enters into a new era of manufacturing partnerships with contract manufacturing organizations (CMOs) in preparation for post-approval product launch of leronlimab, a knowledgeable Head of Quality is a critical component of the BLA approval and the commercialization process. Mr. Bitar brings to CytoDyn over 25 years in quality management, technical operations, pharmaceutical manufacturing and R&D, including most recently as the Global Head of Quality at Hitachi Chemical Advanced Therapeutics Solutions, a cellular and gene therapy contract development and manufacturing organization. Previously, Mr. Bitar led Pfizer's generic

oncology and biosimilars manufacturing through the approval process and was the Site Head of Quality for Pfizer's specialty injectable and biologic drug products. Prior to Pfizer, Mr. Bitar was Vice President – Head of Quality at InnoPharma Inc., which was acquired by Pfizer. Mr. Bitar earned an M.S. in Pharmaceutical Chemistry with Honors from Seton Hall University and a B.Sc. in Chemical Biology (pre-med) with Honors from the Stevens Institute of Technology.

"We welcome Brendan and George to the CytoDyn team at this important point in our corporate trajectory," stated Nader Pourhassan, Ph.D, CytoDyn's President, CEO and director. "With our lead asset now in the final stages of our BLA submission and our agreement with Samsung BioLogics for future commercial manufacturing of leronlimab, the timing is ideal to have Brendan's and George's deep experience on the team, as we implement our commercialization plan and pursue new potential strategic agreements," Dr. Pourhassan continued. "We remain highly encouraged by the potential commercialization of leronlimab as a combination therapy for HIV and its future prospects as a monotherapy, as well as the many other indications, including Phase 2 trials for metastatic triple-negative breast cancer and GvHD, to potentially create significant and enduring value for all shareholders," concluded Dr. Pourhassan.

About Leronlimab (PRO 140)
The U.S. Food and Drug Administration (FDA) has granted a "Fast Track" designation to leronlimab as a combination therapy with HAART for HIV-infected patients and for metastatic triple-negative breast cancer. Leronlimab 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 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 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 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 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 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 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, 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 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 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. 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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