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CytoDyn Announces Promising Survival Observations in mTNBC Patients Treated with Leronlimab

VANCOUVER, Washington, Feb. 24, 2025 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, today announced encouraging survival outcomes among a group of patients with metastatic triple-negative breast cancer (“mTNBC”) treated with leronlimab. Although mTNBC typically has a poor prognosis, observed survival rates at 12, 24, and 36 months after treatment with leronlimab compare favorably with reported life expectancy after treatment with currently approved therapies. In addition, the Company confirmed that a small group of patients who failed treatment after developing metastatic disease survived more than 36 months after receiving leronlimab, are alive today, and currently identify as having no evidence of ongoing disease.

Following the resolution of the Company’s dispute with its former CRO, CytoDyn obtained follow-up records from patients treated with leronlimab during the Company’s prior clinical trials in oncology. After confirming these patient outcomes, CytoDyn worked with consultants and key opinion leaders to summarize the findings and submit an abstract to the European Society for Medical Oncology (ESMO) Breast Cancer meeting taking place in Munich, Germany, from May 14 to 17, 2025.

“We are encouraged by the longer-term survival data to pursue this potentially paradigm-shifting therapeutic pathway for patients suffering from metastatic triple-negative breast cancer,” said Richard Pestell, MD, PhD, AO, the Company’s Lead Consultant in Preclinical and Clinical Oncology. “As a cancer therapeutic, leronlimab was well tolerated with remarkably infrequent treatment-related adverse events. These promising results suggest further studies with leronlimab are warranted to expand oncology treatment options and improve patient care.”

Dr. Jacob Lalezari, CEO of CytoDyn, added: “These provocative observations of improved survival in patients with mTNBC and prior treatment failure in the metastatic setting, including reported clearance of disease in a group of long-term survivors, provides early clinical evidence of leronlimab’s potential impact in the treatment of TNBC and other solid tumors. I expect the Company’s oncology efforts to accelerate in the coming months, with further announcements in both mTNBC and colorectal cancer.”

Based on these survival observations, the Company has initiated two pre-clinical studies in mTNBC that will evaluate possible treatment synergies between leronlimab, an antibody-drug complex treatment (sacituzumab govitecan), and an immune checkpoint inhibitor (pembrolizumab). The Company will also continue to perform follow-up testing on the group of mTNBC survivors who currently identify as having no evidence of ongoing disease.

About CytoDyn

CytoDyn is a clinical-stage biotechnology company focused on the development and commercialization of leronlimab, an investigational humanized IgG4 monoclonal antibody (mAb) that is designed to bind to C-C chemokine receptor type 5 (CCR5), a protein on the surface of certain immune system cells that is believed to play a role in numerous disease processes. CytoDyn has studied leronlimab in multiple therapeutic areas, including infectious disease, oncology, and autoimmune conditions.

Note Regarding Forward-Looking Statements

This news release contains forward-looking statements relating to, among other things, product development, market position, future operating and financial performance, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future events. For important information about these statements and our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review our Annual Report on Form 10-K for the fiscal year ended May 31, 2024, including the section captioned “Forward-Looking Statements” and in Item 1A. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments.

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