October 28, 2022

CytoDyn Announces Voluntary Withdrawal of BLA for HIV-MDR Due to CRO Data Management Issues

Company to complete and submit responses to FDA clinical hold

Continues to study leronlimab in other HIV-related, NASH, and oncology indications

Webcast to be held Monday, October 31, 2022, at 5:30 AM PT / 8:30 AM ET

VANCOUVER, Washington, Oct. 28, 2022 (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a CCR5 antagonist with the potential for multiple therapeutic indications, today announced that it has voluntarily withdrawn its pending Biologics License Application (BLA) for leronlimab as a combination therapy in persons living with HIV with resistance to highly active antiretroviral therapy (HAART) in the HIV multi-drug resistant population (HIV-MDR).

The decision to voluntarily withdraw was based on various factors, including systemic issues related to the quality of the data collection and monitoring of the pivotal clinical trials by the clinical research organization (CRO) contracted to manage the trials, resulting in significant concerns with achieving a successful U.S. Food and Drug Administration (FDA) BLA approval. The Company is of the opinion that FDA approval for the HIV-MDR indication is not feasible without significant additional investment to remedy the issues. CytoDyn plans to publish soon the safety and efficacy data in which it met its primary endpoint, in its Phase 2b/3 randomized, double-blinded, placebo-controlled trial for the HIV-MDR population, in a peer-reviewed journal.

The Company believes the data it currently possesses is sufficient to complete and submit its responses to the FDA to seek the removal of the clinical hold placed on the Company's HIV program. Further, the Company will continue to leverage the performance of leronlimab in these and other studies to advance leronlimab in other HIV-related, non-alcoholic steatohepatitis (NASH), and oncology indications – where compelling data has been generated – that may benefit a greater number of patients and result in significant shareholder value creation. For example, the Company plans to continue to pursue other underserved HIV-related indications, where it can potentially be first to market.

Cyrus Arman, Ph.D., President of CytoDyn, stated, "We have decided to voluntarily withdraw our BLA for the HIV-MDR population at this time only after extensive review and deliberation, including audits from three external independent regulatory quality firms. While the Company met its primary endpoints in these pivotal trials, which we think is a clear indication that leronlimab performs well in the clinic, we believe the issues identified in each of the three independent audits related to the quality of the data collection and oversight by the CRO make it difficult to support a successful BLA regulatory submission. Further, we have filed a claim against the CRO seeking damages resulting from its breach of the Master Services

Agreement and related agreements and reimbursement of our attorney fees and costs associated with the action. As previously discussed, we are focusing on continued development in other HIV indications, NASH, and oncology, where we have Fast Track designation for metastatic triple-negative breast cancer. We plan to reenter the clinic in those indications and believe these steps will allow us to further build on the strong signals we have seen in these indications. I am very excited and quite optimistic about these opportunities, which are what ultimately attracted me to leronlimab and CytoDyn. I believe we have a unique opportunity to impact a significant number of patient lives while creating long-term value for our shareholders."

Tanya Urbach, CytoDyn Board Chair, said, "While this is a difficult decision, the Board supports management and believes this is the best path forward for the Company, study participants, and shareholders. We are grateful to have the expertise of Dr. Arman and our new Board members to identify, evaluate, and guide the Company through difficult decisions such as these to advance successful regulatory approvals. We are very excited about the potential and future promise of leronlimab; the management team and Board are committed to execution."

Webcast Information
The Company will host the following live webcast to discuss these regulatory and clinical updates:

Date: Monday, October 31, 2022
Time: 5:30 am PT / 8:30 am ET
Access: https://event.choruscall.com/mediaframe/webcast.html?webcastid=ie4EeTnh

The replay will be available approximately 60 minutes after the conclusion of the webcast and can be accessed via the above link until December 1, 2022.

About the HIV-MDR BLA and withdrawal of the BLA Submission
The Company pursued the regulatory approval of leronlimab in HIV-MDR based on positive data from its Phase 2b/3 clinical trial for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients, as well as information discussed in meetings with the FDA. In July 2020, the Company received a Refusal to File letter from the FDA regarding its BLA submission for leronlimab as a combination therapy with HAART for highly treatment-experienced HIV patients. The FDA informed the Company that the BLA did not contain certain information and data needed to complete a substantive review, and therefore, the FDA would not file the BLA. The deficiencies cited by the FDA included administrative deficiencies, omissions, data presentation and related analyses, and clarifications regarding the manufacturing processes. In November 2021, the Company resubmitted the non-clinical and chemistry, manufacturing, and controls (CMC) sections of the BLA. As of March 2022, the FDA had commenced its review of the CMC section. The Company is in a legal dispute with its former CRO, which was engaged to manage the clinical trials. In the context of the litigation, the Company obtained an order requiring the CRO to release the Company's clinical data related to the BLA and other clinical trials, which the CRO had been withholding. Further, the order granted the Company the right to perform an audit of the CRO's services. Additionally, in March of 2022, the FDA placed the HIV program on a partial clinical hold, which could affect our ability to resubmit the BLA. The Company performed evaluations of the data, results of the audits, and implications of the

partial clinical hold. The Company determined the likelihood of FDA approval of the BLA was low and voluntarily withdrew its BLA due to issues with the quality of the collection and monitoring of the data by the CRO contracted to manage the clinical studies and the costs needed to remedy the issues. However, the Company believes it does possess the necessary data to submit to the FDA in connection with its response to the clinical hold on the HIV program.

About NASH and leronlimab

The Company is identifying next steps in clinical development to continue the investigation of leronlimab in NASH. The potential for leronlimab in the treatment of NASH was demonstrated in a pre-clinical model of fatty liver disease. Immunodeficient, NOD-SCID Gamma (NSG) mice were fed a high-fat, NASH-inducing diet, transplanted with human stem cells to repopulate the deficient immune system, and treated with leronlimab. Sixteen (16) male NOD.Cg-Prkdcscid Il2rgtm1Wjl/SzJ, commonly known as the NOD scid IL-2 receptor gamma knockout mice (NSG), were first humanized by intravenous inoculation with normal human umbilical cord blood cells (105). After five weeks on normal mouse chow, mice were successfully humanized, demonstrating >25% human CD45 cells in peripheral blood. Mice were switched to high fat (52%) high cholesterol (1.25%) diet (FPC diet: fructose, palmitate, cholesterol, trans-fat; Envigo-Teklad TD.160785). Leronlimab and control antibody (normal human IgG, Sigma) were administered i.p. at a dose of 2mg i.p. twice weekly, n=8 mice/group. The results showed that leronlimab inhibited fatty liver development, a key characteristic of early-stage NASH, such that treatment of humanized NSG mice with leronlimab caused a threefold reduction in hepatic steatosis compared to control in an animal model of high fructose, high palmitate, high cholesterol diet.

The Company has reported clinical data from patients with NASH from the CDI-NASH-01 trial, which was designed as a multi-center Phase 2a study to evaluate the dose, efficacy, and safety of leronlimab at 350 mg and 700 mg, versus placebo. The study also included an expansive biomarker program designed to inform future clinical trials and to understand leronlimab's mechanism of action more fully within the NASH setting. CDI-NASH-01 was run in two parts. Part 1 of the study was to assess the efficacy of leronlimab 700 mg (n=22) in improving NAFLD/NASH measures in adult patients diagnosed with NASH compared to placebo (n=28). Part 2 was subsequently added to assess leronlimab 350 mg in improving NAFLD/NASH measures in adult patients diagnosed with NASH (n=22). In Part 1 of the study, eligible subjects were randomized 1:1 to one of the two study arms to receive either leronlimab 700mg (Group A), or placebo (Group B), given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 60 participants). In Part 2 of the study, eligible subjects enrolled to receive leronlimab 350 mg open-label given once per week (±1day) at the study site for up to 13 weeks during the treatment period (with up to 28 participants). The primary efficacy objective was percent change from baseline in hepatic fat fraction, as assessed by magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF) at week 14. The secondary efficacy objective was absolute change from baseline in fibro-inflammatory activity in the liver as assessed by MRI-corrected T1 imaging (MRI-cT1) at week 14. MRI-cT1 is obtained by multiparametric magnetic resonance imaging of the liver and is a quantitative metric for assessing a composite of liver inflammation and fibrosis, expressed in milliseconds (msec). MRI-PDFF is being studied as an imaging surrogate endpoint for the fat density in the liver. MRI-cT1 is being studied as an imaging surrogate endpoint for hepatic fibro-inflammation. This is a critical unmet need in the NASH space, as many agents have been unable to show reductions in fibro-inflammation despite

reductions in hepatic steatosis.

All analyses performed were exploratory. Treatment with leronlimab was well tolerated in both Part 1 and Part 2 compared to placebo. In Part 1 of the study, leronlimab 700 mg did not reduce mean change in PDFF and cT1 from baseline to week 14 vs. placebo. In Part 2, leronlimab 350 mg reduced mean change in PDFF and cT1 from baseline to week 14 vs. the placebo group from Part 1, despite increased degree of baseline fibro-inflammation. In the combined group of patients with moderate (≥ 875 msec) and severe (≥ 950 msec) cT1 values at baseline, leronlimab 350 mg reduced cT1 from baseline to week 14 vs. placebo. Based on post hoc CCR5 haplotype analysis of a small subgroup (n=5), we are considering further investigation of the 700mg dose of leronlimab for specific haplotypes.

About oncology and leronlimab
The Company is identifying the next steps in clinical development and is exploring potential business opportunities, for the investigation of leronlimab to treat solid tumors in oncology based on data generated to date by the Company. To assess the impact of leronlimab treatment on mTNBC patients, we pooled the data from 3 studies: CD07_TNBC Phase 1b/2, CD07_TNBC_Compassionate Use, and CD-09 Basket. The study population for pooled efficacy analysis was a total of 28 subjects (10 subjects from the Phase 1b/2 study, 16 subjects from the Compassionate Use Study, and 2 subjects from the Basket Study).

To explore the impact of leronlimab in the mTNBC patients' disease progression, investigator assessed Progression Free Survival (PFS) was analyzed in the 28 subjects. There was a total of 19 subjects dosed between 525 mg and 700 mg (4 subjects increased dose from 350 mg to 525 mg and were included in the higher dose cohort). The median PFS (mPFS) for the 525 mg – 700 mg cohort was 6.2 months (95% CI 2.6 months - 7.5 months). There were 9 subjects dosed at 350 mg, mPFS was 2.2 months (95% CI 0.7 months - 12+ months). There was a meaningful PFS advantage at the higher doses when compared with the lower, 350 mg dose cohort. Furthermore, the preliminary results of the leronlimab studies also showed similarity in the PFS outcomes of mTNBC patients treated with leronlimab + carboplatin compared to overall leronlimab treated population. Of the 28 subjects enrolled, 13 subjects received leronlimab + carboplatin treatment. The mPFS for leronlimab + carboplatin population was 3.9 months (95% CI 2.3 months - 6.0 months). The subgroup analysis of PFS based on the individual subjects in each study was also reviewed. The mPFS for Phase 1b/2 study was 3.9 months (95% CI 2.3 months – 6.2 months), mPFS for the Compassionate Use study was 3.3 months (95% CI 1.3 months – 7.5 months), and mPFS for the Basket Study was 2.8 months (95% CI N/A). Combined, the overall mPFS for all 28 patients treated with leronlimab in the population of mTNBC patients regardless of dosage, conjunction therapy type, brain or bone metastases that have failed more than one line of previous therapy was 4.1 months (95% CI 2.5 months – 7.0 months). The mean PFS was 3.7 ± 2.93 standard deviation (SD).

To explore the impact of leronlimab in the mTNBC patients' disease progression, Overall Survival (OS) was analyzed in the same 28 subjects. The median OS (mOS) for leronlimab + carboplatin population was 12+ months (95% CI 5.4 months - 12+ months). The mOS for the 350 mg cohort was 4.6 months (95% CI 1.1 months -12+ months). The mOS for the 525-700 mg cohort was 12+ months (95% CI 5.5 months – 12+ months). The overall median OS for leronlimab treated population of mTNBC patients regardless of brain or bone metastases that have failed more than one line of previous therapy was 6.5 months (95% CI 5.0 months

– 12+ months). The mean value for OS was 5.5 ±4.31 standard deviation (SD).

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 is studying leronlimab in multiple therapeutic areas, including infectious disease, cancer, and autoimmune conditions.

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. Forward-looking statements may include statements about leronlimab, its ability to provide positive health outcomes, the Company's ability to develop a successful operating strategy and thereby create shareholder value, the possible results of clinical trials, studies or other programs or ability to continue those programs, the ability to obtain regulatory approval for commercial sales, and the market for actual commercial sales. 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 regulatory determinations of leronlimab's safety and effectiveness to treat the diseases and conditions for which we are studying the product by the U.S. Food and Drug Administration (FDA) and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (iv) the Company's ability to recruit a permanent CEO and retain other key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third-parties; (vi) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vii) the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with applications for approval of the Company's drug product; (viii) the Company's ability to achieve approval of a marketable product; (ix) the design, implementation and conduct of the Company's clinical trials; (x) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (xi) the market for, and marketability of, any product that is approved; (xii) 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; (xiii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiv) legal proceedings, investigations or inquiries affecting the Company or its products; (xv) general economic and business conditions; (xvi) changes in foreign, political, and social conditions; (xvii) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xviii) 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 subsequent Form 10-Qs and Form 8-Ks, 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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