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CytoDyn Announces Completion of FDA Meeting on Phase II Study of Leronlimab in Patients with Relapsed/Refractory Microsatellite Stable Colorectal Cancer

VANCOUVER, Washington, Aug. 12, 2024 (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, announced today that it completed a meeting with the U.S. Food and Drug Administration (FDA) to gain alignment on the rationale and proposed dosing for the Company's Phase II study that will investigate the preliminary safety and activity of leronlimab in combination with trifluridine plus tipiracil (TAS-102) and bevacizumab in participants with CCR5+, microsatellite stable (MSS), relapsed or refractory metastatic colorectal cancer (mCRC).

The Company intends to proceed with a submission of its final study protocol to the FDA, formal engagement of a clinical research organization (CRO), and related preparatory work towards initiating the proposed trial.

This open label, randomized (1:1), multicenter trial will evaluate the anti-tumor activity (via overall response rate, ORR) of leronlimab at doses of 350 mg and 700 mg in combination TAS-102 and bevacizumab in approximately 60 patients with CCR5+, microsatellite stable metastatic CRC (mCRC).

Patients enrolled in the trial must have measurable disease per RECIST v1.1 and have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy. CCR5 tumor expression will be determined by immunohistochemistry assay (IHC) and diagnosis of MSS CRC will be confirmed by IHC or next-generation sequencing (NGS).

TAS-102 and bevacizumab will be administered for three of four weeks in a four-week cycle, and leronlimab (at doses of 350 mg or 700 mg) will be administered weekly. The study will include a safety lead-in treating five patients in the 350 mg leronlimab arm prior to beginning enrollment to the 700 mg leronlimab arm.

"We are pleased to have received the FDA's feedback on our Phase II study of leronlimab in patients with relapsed/refractory microsatellite stable colorectal cancer, and remain on track to commence our oncology trial in the coming months. Advancing leronlimab in the oncology indication has been an important priority for our team as we progress CytoDyn's clinical pipeline," said Dr. Jacob Lalezari, CEO.

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 developing leronlimab in multiple therapeutic areas, including oncology and inflammation.

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 implement a successful operating strategy for the development of leronlimab and thereby create shareholder value, the ability to obtain regulatory approval of the Company's drug products for commercial sales, and the strength of the Company's leadership team. 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 (the "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 and other payment obligations; (iv) the Company's ability to recruit and retain key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third parties; (vi) 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; (vii) the Company's ability to achieve approval of a marketable product; (viii) the design, implementation and conduct of the Company's clinical trials; (ix) the results of any such clinical trials, including the possibility of unfavorable clinical trial results; (x) the market for, and marketability of, any product that is approved; (xi) 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; (xii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiii) legal proceedings, investigations or inquiries affecting the Company or its products; (xiv) general economic and business conditions; (xv) changes in foreign, political, and social conditions; (xvi) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xvii) 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 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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