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# CytoDyn Signs Distribution Agreement with Macleods Pharmaceuticals Ltd. to Pursue EUA and Compassionate Use Access to Leronlimab in India

*Macleods is one of the largest pharmaceutical companies in India with presence in over 140 countries*

VANCOUVER, Washington, May 13, 2021 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTC.QB: CYDY)**, ("CytoDyn" or the "Company"), a late-stage biotechnology company developing leronlimab (Vyrologix or PRO 140), a CCR5 antagonist with the potential for multiple therapeutic indications, announced today it has executed an exclusive supply and distribution agreement with Macleods Pharmaceuticals Ltd. in India. This commercial agreement will enable Macleods to sell leronlimab in India following regulatory clearance.

Nader Pourhassan, Ph.D., President and Chief Executive Officer of CytoDyn, stated, "We are delighted Macleods Pharmaceuticals reached out to CytoDyn and equally excited to reach this agreement with their team so quickly. From the time they first contacted us about our drug, we were able to conclude this agreement within a few days. It is an honor to work with an organization so motivated to bring leronlimab to COVID-19 patients in India. Currently India has zero product approved for critically ill Covid-19 patients and we are delighted to be working toward being the first approved drug for this population."

Vijay Agarwal, a Business Development Director at Macleods, commented, "We are thrilled with our recently executed exclusive supply and distribution agreement with CytoDyn. We believe there is an immediate need for leronlimab in our country, to save COVID-19 infected patients who are on ventilators. We need to bring this product to market ASAP for them!"

## **About Macleods Pharmaceuticals Ltd.**

Macleods, headquartered in Mumbai, India, is a vertically integrated, global pharmaceutical company. Established in 1986, Macleods features in top 10 pharmaceutical companies in India. Macleods specializes in the development and manufacturing of active pharmaceutical ingredients and finished dosage pharmaceutical formulations. More information is available at [www.macleodspharma.com](http://www.macleodspharma.com).

## **About Leronlimab (PRO 140)**

Leronlimab has been studied in 11 clinical trials involving more than 1,200 people and met its primary endpoints in a pivotal Phase 3 trial (leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients).

Leronlimab is a viral-entry inhibitor in HIV/AIDS. It masks CCR5, thus protecting healthy T

cells from viral infection by blocking the predominant HIV (R5) subtype from entering those cells. Nine clinical trials have demonstrated leronlimab could significantly reduce or control HIV viral load in humans. The leronlimab antibody appears to be a powerful antiviral agent with fewer side effects and less frequent dosing requirements than currently used daily drug therapies.

CytoDyn has successfully completed a Phase 3 pivotal trial using leronlimab combined with standard antiretroviral therapies in HIV-infected treatment-experienced patients. CytoDyn has been working diligently to resubmit its Biologics License Application ("BLA") for this HIV combination therapy since receiving a Refusal to File letter in July 2020 and subsequently meeting with the FDA telephonically to address their written guidance concerning the submission. CytoDyn expects to resubmit its BLA via a rolling submission starting in the third quarter of calendar 2021.

### **About CytoDyn**

CytoDyn is a late-stage biotechnology company developing innovative treatments for multiple therapeutic indications using leronlimab, a novel humanized monoclonal antibody targeting the CCR5 receptor. CCR5 appears to play a critical role in the ability of HIV to enter and infect healthy T-cells. More information is at [www.cytodyn.com](http://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. Forward-looking statements specifically include statements about leronlimab, its ability to provide positive health outcomes, 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 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.

## **CONTACTS**

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