Dear Dr. Woodcock,

The FDA has protected the American public during Covid by issuing various EUAs, but no treatment has been advanced that specifically helps our most vulnerable citizens-those who are critically ill. And unfortunately, with variant strains now circulating, a potential 4th wave is possible.

CytoDyn's CD12 trial is the first randomized, double-blind, placebo-controlled study to suggest a striking survival benefit for critically ill Covid patients (24% reduced mortality; p value nss). The study demonstrates statistical significance on a number of crucial secondary endpoints including shortened hospital stay in all critically ill patients (6 days; P=0.005) and improved survival in all patients who received SOC therapy (N=309; P=0.031). The study also demonstrated no safety concerns, consistent with the benign safety profile seen in about 1,000 other HIV+, cancer, and Covid patients who have received leronlimab. The unfortunate imbalance in randomization of patients > 65 years of age (and especially $\geq$ 75 years) in the CD12 study should not, however, prevent patient access to a potentially life saving medication now while a study of additional critically ill patients is underway. Taken together, the CD12 efficacy signals in critically ill patients combined with the consistently benign safety profile, provide a compelling risk:benefit ratio and ample justification for FDA to issue an EUA for leronlimab for this population now.

I am consulting in the care of a 57 year old man with critical Covid who was on ECMO for 61 days at St. Thomas hospital in London. He received emergency leronlimab on day 79 of his hospitaliztion and starting weaning off ECMO 4 days later. I have attached the case report below, which has been peer reviewed and accepted for publication. Please give it your consideration. Though anecdotal, this case underscores the dramatic recovery that is possible with leronlimab even in the most critically ill patients with Covid.

I have been an independent investigator on about 50 POC studies of novel antiviral agents over the last 31 years (including HIV, CMV, HCV, HBV, HSV, HPV, and Influenza). Also, I have no equity stake in this.

I know leronlimab to be safe and I believe it can help save critically ill patients with Covid-19.
Please give these patients and their medical teams a fighting chance.

Respectfully,

Jacob Lalezari, MD
Director, Quest Research
SF, CA