From: Jay Lalezari, Quest Clinical Research
Subject: Hope for Critical Covid-19 Patients
Date: November 29, 2021 at 12:43:59 PM PST
To: Wendell Primus
Cc: Matthew Fuentes, Mike Jean, Jared Huffman , Jenny Callaway Janet Woodcock, Jeffrey S Murray, Kimberly Struble, Debra Birnkrant, Marcella Nunez-Smith, Xavier Becerra, Christopher Recknor, Nader Pourhassan, Scott Kelly

Dear Offices of Senator Schumer, Speaker Pelosi, Rep. Huffman, and Colleagues,

I write today to request that NIH review CytoDyn's development program for leronlimab for treatment of critical patients with Covid-19.

As described in an earlier email, a Phase III study of leronlimab demonstrated an 82% reduction in death at Day 14 in a subgroup of 62 critical Covid-19 patients (intubated, on mechanical ventilation) who received 2 weekly doses of leronlimab compared to placebo. Leronlimab treated patients were also 166% more likely to be discharged alive at Day 28 compared to placebo. Per FDA guidance, a larger follow up study is still required to confirm the statistical significance of these observations before regulatory action can proceed. That follow up study was launched by CytoDyn in September in Brazil.

Leronlimab is a monoclonal antibody with a proposed mechanism of action that specifically targets the hyperinflammation or "cytokine storm" of severe Covid-19. In contrast to other treatments, which must be given early after infection to provide meaningful benefit, leronlimab is designed to help the most severely ill Covid-19 patients and the ICU teams struggling to care for them. Equally important, since leronlimab targets immune dysfunction rather than the virus itself, it should remain active against mutant strains of virus.

Unfortunately, CytoDyn announced on November 24th they have only enrolled 4 patients in the Brazil study over the preceding 2 months. Given this slow rate of enrollment, coupled with the emerging threat of the Omicron variant, I believe it is imperative that NIH now get involved. CytoDyn is a small company facing many challenges and lacking the resources to meet the urgent needs of this moment. My hope is that colleagues at NIH can review CytoDyn's current clinical data and provide guidance to their overall development plan.

Dr. Chris Recknor, cc'd above, is the COO at CytoDyn and has indicated he would welcome input from NIH. I request that you identify the appropriate person or group at NIH to consult with Dr. Recknor and the team at CytoDyn to provide this urgently needed assistance.

Thank you for your efforts on behalf of the American people at this crucial juncture.

Kind regards,

Jacob Lalezari, MD
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ps-I have been a principal investigator on dozens of antiviral development programs over the past 33 years. Quest Research receives funding from CytoDyn for our work on their HIV and cancer programs, and I briefly served as their Interim Chief Medical officer in 2020. I do not own stock, receive other compensation, or have any other financial stake in the company.