September 22, 2021

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

Thank you for your support during the development of leronlimab for the treatment of Covid-19.

As you recall, a recent study of leronlimab demonstrated an 82% reduction in death at Day 14 in a group of 62 critical Covid-19 patients (intubated, on a ventilator) who received 2 weekly doses of leronlimab compared to placebo. Per FDA guidance, a follow-up study is required to confirm the significance of this observation before regulatory action can be taken. I am writing today to alert you that the required confirmatory study is now approved for enrollment with details in the press release below.

The study is being run in Brazil under the auspices of the Albert Einstein Israelite Hospital. The study will enroll 316 critical patients with an interim analysis planned after 40% enrollment. A second study of 612 hospitalized Covid-19 patients on oxygen but not yet on mechanical ventilation is also underway.

As previously discussed, leronlimab is a monoclonal antibody that has been safely given to over 1,200 individuals including patients with Covid-19, HIV or cancer. The drug is specifically designed to treat the immune imbalance ("Cytokine storm") associated with severe Covid-19. Importantly, given the proposed mechanism of action, it is believed leronlimab will remain effective against mutant strains of virus such as Delta (and Mu). Concerns about waning immunity following vaccination or natural infection have refocused attention on the challenges of treating severe Covid-19 illness. Our colleagues at FDA (cc'd above), and others concerned about this urgent unmet need, anxiously await the results from Brazil. Please let me know if I can provide any further information.

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