May 28, 2020

To: HERO HCQ Randomized Controlled Trial Study Leadership

FROM: DSMB, HERO HCQ Trial

RE: Results of an unscheduled DSMB meeting for the HERO HCQ Trial

The DSMB for the HERO HCQ Trial met on May 28, 2020 for an unscheduled meeting.

Our purpose was to review public reports addressing the safety (not efficacy) of HCQ. We reviewed available data in the peer-reviewed public domain including observational analyses recently published in JAMA (Rosenberg, ES et al. Association of Treatment With Hydroxychloroquine or Azithromycin With In-Hospital Mortality in Patients With COVID-19 in New York State. May 11, 2020.), NEJM (Geleris, J et al. Observational Study of Hydroxychloroquine in Hospitalized Patients with Covid-19. May 7, 2020.), and the Lancet (Mehra et al. Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis. May 22, 2020.). We also reviewed privileged communications from study leadership for other major trials addressing the use of HCQ and in turn ascertaining safety data. The aggregate of published and unpublished data was reviewed in Open Session with Study Leadership and deliberated further in Closed Session.

Our unanimous decision is to continue the HERO HCQ Trial as per protocol without modifications, and with continued safety review as per our already defined DSMB meeting and review schedule.

Respectfully submitted,

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Chair, HERO HCQ Trial Data Safety and Monitoring Board
On behalf of the members of the DSMB, HERO HCQ Trial