U.S. FOOD & DRUG ADMINISTRATION

April 12, 2021

Aaron Siri
Siri & Glimstad, LLP
200 Park Avenue, 17th Floor
New York, NY 10166

Sent via email to: aaron@sirillp.com

Re: Docket No. FDA-2020-P-1768

Dear Mr. Siri,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet reached a resolution of the issues raised in your amended citizen petition received by the Dockets Management Staff on October 16, 2020. Your amended petition, submitted on behalf of the Informed Consent Action Network (ICAN), requests that FDA amend the study design for the Phase III trial of ChAdOx1nCoV-19 (NCT04400838) to provide that:

a. any and all adverse events and reactions will be documented for the entire duration of the trial;

b. such documenting of adverse events and reactions shall last at least twenty-four months for adults, thirty-six months for children, and sixty months for infants and toddlers or such longer duration as appropriate, and in no event end prior to the subject reaching eight years of age;

c. it uses an adequate sample size, appropriately powered, in order to (i) detect an increase in rare adverse events or any untoward medical occurrence, whether or not considered vaccine related, and (ii) determine that the rate of adverse events from the vaccine will not exceed the rate of adverse events known to occur from SARS-CoV-2 in the group under review;

d. participants are tested for T-cell reactivity to SARS-CoV-2 pre-vaccination and post-vaccination;

e. germline transmission tests are conducted for male participants; and

f. HIV incidence will be "monitored at the end of the study and for an appropriate follow-up period" and the trial will "evaluate the levels and distribution of both vector and insert responses in target tissues where HIV acquisition is known to occur."

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Because of the existence of other FDA priorities, we have not been able to reach a decision on the petition at this time. This interim response is provided in accordance with FDA's regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research

cc: Dockets Management Staff