Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Pharmaceutical Drugs Directorate
Office of Clinical Trials
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A/L 3105A
1600 Scott Street
Ottawa, Ontario
Canada K1A 0K9

2 November 2022

Unity Health Toronto - Dr. Andrew Pinto
c/o Gurpreet Lakhanpal
Manager, Clinical Trials
Applied Health Research Centre (AHRC), Unity Health Toronto
30 Bond Street
TORONTO, Ontario
M5B 1W8
(416) 864-6060 Ext. 47835

Dossier ID: HC6-024-c269011
Control #: 269011

Notice of Authorization

Dear Gurpreet Lakhanpal:

The Clinical Trial Application for **NIRMATRELVIR / RITONAVIR**, Control # **269011** received on 25 October 2022, concerning Protocol **CanTreatCOVID-1 to V 1.4 dated 28 October 2022 (Includes Amendment #1); CanTreatCOVID - Amendment Tracker v1.2 dated 28 October 2022 (Includes Amendment #1); Intervention Specific Sub-Protocol: Paxlovid™ x 5 days to v1.1 dated 28 October 2022** has been reviewed.

Authorization of this trial is hereby issued as per Section 21 of the *Clinical Trials for Medical Devices and Drugs Relating to COVID-19* (the Regulations) pursuant to subsection 30 of the *Food and Drugs Act.* Please consider this as your notice of authorization to sell or import the COVID-19 drug(s) that are to be tested in the clinical trial and to conduct the clinical trial in respect of the drug(s) in Canada.

The clinical trial authorization holder is reminded of the requirements in the Regulations: to conduct all clinical trials in accordance with Good Clinical Practice as per section 28, to apply to amend the authorization where necessary as per section 24(2) and 24(4), to report any serious unexpected adverse reactions to Health Canada as per section 34, and to maintain records as per section 35. Please consult the Regulations or the "Guidance on applications for COVID-19 drug clinical trials under the Regulations" for additional details regarding post authorization requirements.

Reports for all serious and unexpected Adverse Drug Reactions (ADRs) should be:

- faxed to 613-941-2121 (for therapeutics only); or
- submitted electronically via the E2B Electronic Gateway. This method is recommended if your company/institution has electronic gateway capability. Please contact the Trading Partner Management Office (TPMO) by email at tpmo-bgpc@hc-sc.gc.ca for more information.

The Pharmaceutical Drugs Directorate requests that the authorization holder register their COVID-19 clinical trial and notify the Directorate by sending an email to oct.enquiries-requetes.bec@hc-sc.gc.ca within 5 days of registration. The email should include "COVID-19 clinical trial registration" in the subject line and provide the following information:

- Clinical trial registry name;
- Link to clinical trial posting; and
- Registration number (e.g., Clinicaltrials.gov Identifier – NCT#).

In accordance with Section 27 of the Regulations, the following drug(s) is exempted from the labelling requirements under section 33 and the records requirements under paragraphs 35(2)(a) to (c) of the Regulations :

Nirmatrelvir / Ritonavir

In accordance with Section 22 of the Regulations, a completed Clinical Trial Site Information Form for each Canadian site should be emailed to clinical.trials.site-lieu.essai.clinique@hc-sc.gc.ca prior to initiating the trial at that site.

Failure to comply with requirements of the Regulations may result in suspension or cancellation of this authorization, as per sections 29 and 32.

Should you have any questions concerning this letter, please contact the Office of Clinical Trials at oct.enquiries-requetes.bec@hc-sc.gc.ca .

Sincerely,

This document has been signed electronically using the Health Canada docuBridge system.

Dr. Michael Leonard, MD, FRCSC
Manager, Office of Clinical Trials