Medicines & Healthcare products Regulatory Agency

MHRA

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Ms Heather House
UNIVERSITY OF OXFORD
CLINICAL TRIALS AND RESEARCH GOVERNANCE, JOINT RESEARCH OFFICE,
1ST FLOOR, BOUNDARY BROOK HOUSE, CHURCHILL DRIVE, HEADINGTON
OXFORD
OX3 7LQ
UNITED KINGDOM

17/03/2020

Dear Ms Heather House,

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 21584/0423/001-0001
Eudract Number:	2020-001113-21
Product:	Lopinavir/ritonavir, Dexamethasone, Interferon beta-1a
Protocol number:	NDPHRECOVERY

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 13/03/2020.

PHARMACEUTICAL - Remarks: Pharmaceutical conditions of approval
1. No participants will be recruited to Arm 3: Interferon-Beta-1a until an updated QP declaration and an appropriate labelling strategy for SNG001 has been submitted and approved.
If these conditions are met, the trial is authorised and you do not need to respond to this letter. If your trial does not meet these conditions, your trial does not have authorisation and therefore you cannot proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above conditions. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation.
If you have a query on these comments, please contact Fiona Law on 020 3080 6248 or Fiona.law@mhra.gov.uk.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed.

Yours sincerely,

Clinical Trials Unit
MHRA

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