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Dr J Cheriyan CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST HILLS ROAD, CAMBRIDGE CB2 0QQ UNITED KINGDOM

08/06/2020

Dear Dr J Cheriyan,

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

Our Reference: Eudract Number: Product: Protocol number: CTA 12854/0251/001-0001 2020-002229-27 Forxiga 10mg (Dapagliflozin), Ambrisentan , EDP1815 TACTIC-E

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 27/05/2020.

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