Supplementary Material 13

Medicines and Healthcare products Regulatory Agency Clinical Trial Authorisation Approval

MHRA

Regulating M•<licines ,nd Modical Devices

MHRA

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Dr G Hirschfield
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16/12/2014

Dear Dr G Hirschfield

THE MEDICINESFOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 5.1. 200 4/1031

Our reference:	21761/0311/001-0001
Eudract Number:	2014-002393-37
Product:	BTT1023 IV Infusion 20 mg/ml, 5 ml Drug Product
Protocol number:	RG_13027

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 17/11/2014.

Authorisation of your clinical trial is subject to the following condition(s):

- No reprocessing is undertaken during manufacture of the drug substance.
- The retest date specified on the label will be treated as an expiry date.

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 can not 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.For further information on the above points, please contact Dr Martin O'Kane on 020 3080 6659.

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,

Cli nical Trials Unit
MHRA

Medicines and Healthcare Products Regulatory Agency