Norwegian Medicines Agency

Oslo universitetssykehus HF - Ullevål sykehus
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0424 Oslo
Norge

Exempted from public disclosure cf.
Offl §13 første ledd, jf. fvl. §13 første ledd nr2, jf. lml. §30

Your ref.:	Date:	Our ref.:	Officer:
Dan Atar	31 May 2018	18/02571-12	Anna Randby

CLINICAL TRIAL – BETAMI – EUDRACT NO. 2018-000590-75

Reference is made to correspondence in the above mentioned matter, of latest our letter dated 2018-05-11 and your letter dated 2018-05-31.

The Norwegian Medicines Agency has no objections to the commencement of this trial.

Conclusion: The clinical trial is approved.

We wish you the best of luck with the trial and look forward to receiving annual reports and/or the study report when available.

Please be aware that the approval of a clinical trial application does not encompass any necessary authorisations for manufacturing and/or import. For further information, please refer to our webpages: www.legemiddelverket.no.

The decision of the Norwegian Medicines Agency can be appealed (*see* The Public Administration Act § 28). An appeal should be submitted to the Norwegian Medicines Agency, and must be submitted within three weeks of receipt of this letter, (*see* The Public Administration Act § 29). More information about the right to appeal against an administrative decision, including the notification form, can be found here.

Yours sincerely
Norwegian Medicines Agency

Anna Randby, MD, PhD
Senior Advisor

This document is electronically approved and sent without signature.

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Letters should be addressed to the Norwegian Medicines Agency.
Please state our reference.

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REK Sør-Øst Regional Komité for medisinsk forskningsetikk

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