REMAP-CAP
Randomized, Embedded, Multifactorial Adaptive Platform trial for Community-Acquired Pneumonia

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12/04/22
Re: Study Title: Randomized, Embedded, Multi-factorial, Adaptive Platform Trial for community -Acquired Pneumonia
REC reference: 18/lo/0660
EudraCT number: 2015-002340-14
IRAS project ID: 237150

Substantial amendment 35 (AM35)
I am submitting substantial amendment AM035 for the REMAP-CAP study.
Addition of releasing site information to section D9 of the MHRA CTA for cysteamine.
This involves changes to the MHRA CTA for the Cysteamine stock for use within REMAP-CAP
Addition of UK Releasing site: Catalent CTS (Edinburgh) Limited ,Unit 1, Inchwood Park, Bathgate,West Lothian, EH48 2FY, United Kingdom
Marketing Authorisation holder: Catalent CTS (Edinburgh) Limited ,
MIA (IMP) number: 25274
Submission of associated IMPD V3 08.04.22 (tracked changes and final)
Significant Changes to the IMPD:

1. Page 103: Section 1.1.P.2.2 Manufacturer (S): Added new clinical trial supplier {Catalent CTS (Edinburgh) Limited} details, their responsibilities and QP release under the QP-to-QP agreement
2. Page 168: Primary packaging: added that the new clinical trial supplier will carry out labelling & packaging for unlabelled vials from lot no.P04620
3. Page 222 to 246: Added GMP manufacturing authorisation certificate of Catalent CTS (Edinburgh) Limited
4. Page 247 to 251: Added GMP compliance certificate of Catalent CTS (Edinburgh) Limited
5. Page 252 to 253: Added GDP compliance certificate of Catalent CTS (Edinburgh) Limited

Other minor changes/updates to the IMPD

1. Page8: Corrected the section number for the alternative stability testing laboratory
2. Page 28 & 34: Added lot number for the new reference standard & the CoA for the reference standard
3. Page 86 to 88: Section 2.1.S.7 Stability : added more information on the alternative stability testing laboratory, included stability protocol, stability testing timepoints and post-approval stability protocol and stability commitment by Cambrex Profarmaco Milano for the drug substance
4. Page 178: Added 9m stability results for the GMP batch P04620

I have also attached updated Clinical Trial insurance documentation that extends study insurance to June 2023

The below documents are included in this submission:
MhraProductsForm_REMAP-CAP AM035 110422
Cysteamine_Nylexa IMPD_V3.0_08 Apr 2022_Final
Cysteamine_Nylexa IMPD_V3.0_08 Apr 2022_track changed
REMAP-CAP AM035 Amendment_Tool_v1_6_LOCKED
GB_REMAP-CAP_SubjectInsurance_Allianz_Endorsement 2_20210715
GB_REMAP-CAP_SubjectIsurance_Allianz_Endorsement 1_20210125
Subject Insurance Certificate

Many Thanks
Farah

Digitally signed by Farah Al-Beidh
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