Bellberry Limited supporting research and ethics

129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
Fax: 08 8361 3322

21-Aug-18

Dr. Sepehr Shakib
CMAX
Level 5, 18a North Terrace
Adelaide SA 5000

Dear Dr. Shakib,
Re: Application No: 2018-04-256
Study Title: LYN-057-C-002: An Open Label Study to Evaluate the Safety and Gastric-Retentive Properties of Modified Release Prototype Capsules Containing Memantine Hydrochloride in Healthy Adults
Application Type: NEW
Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

LYN 057-C-002 (CM8718) Endoscopy ICF v 3.0 dated 01AUG 2018
LYN-057-C-002 (CM8718) Protocol V4.0 dated 01 Aug 2018
LYN-057-C-002 (CM8718) Protocol V4.0 dated 01 Aug 2018.PI signature page
LYN-057-C-002 (CM8718) Protocol V4.0 dated 01 Aug 2018.Sponsor signature page
LYN-057-C-002(CM8718) PISICF Part A version 1.0 dated Mar 2016
LYN 057-C-002 (CM8718) Bellberry Imaging Consent Form V 3.0 dated 01 Aug 2018
LYN-057-C-002 (CM8718) Bellberry PICF Part B & C V3.0 dated 01 Aug 2018
LYN-057-C-002_(CM8718) Radiation Report
Lyndra IB Edition 5 dated 11 May 2018 plus EBIXA and Namenda XR
Lyndra Australia Pty - Australia - Certificate Exp 01 Feb 2019
LYN-057-C-002 (CM8718) Radio Script V2 dated 16 April 2018
LYN-057-C-002 (CM8718) Social Media Plan V1.0 dated 05 Feb 2018
LYN-057-C-002 (CM8718) Social Media Advertising V3 dated 15 May 2018 clean
LYN-057-C-002 (CM8718) Site Approval Form dated 16 Apr 2018.
LYN-057-C-002 (CM8718) Site approval form with Ashford

Includes:
- LYN-057-C-002 (CM8718) Lyndra dosage animation video

The Committee noted the following documents:
- Background re Lyndra technology 13 April 2018
- 20180406 Preclinical AH Expert Review FINAL
- Lyndra Pharm Expert report 16 April 2018
- LYN-057-C-002 (CM8718) Lyndra Dosage animation video rationale V1.0 dated 17 Apr 2018
- Final Master Reviewers Checklist_CALHN HREC_Medical Device
- Benson MRI Safety MRI questionnaire F30.V4

As per the Study Sites page of the application, it is noted that the endoscopies for this study are being performed by Dr Alan Wigg at

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the Ashford Hospital, 55 Anzac Highway, Ashford SA 5035

Date of Meeting: 02-May-18
Date of Approval: 21-Aug-18
Period of Approval: 21-Aug-18 - 21-Aug-19

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics Committee (HREC) reviewed this study in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research (2007, incorporating all updates as at May 2015) (National Statement) on the above meeting date.

This Bellberry HREC is constituted and operates in accordance with the National Statement.

I wish to advise that the Bellberry Human Research Ethics Committee has approved this project and that the application meets the requirements of the National Statement subject to the conditions mentioned below.

CONDITIONS:-

- **THAT YOU ACKNOWLEDGE YOUR AGREEMENT TO THE UNDER MENTIONED CONDITIONS BY SIGNING AND RETURNING A COPY OF THIS LETTER, PRIOR TO THE COMMENCEMENT OF THE RESEARCH. THE SIGNED LETTER CAN BE EMAILED TO BELLBERRY@BELLBERRY.COM.AU OR POSTED TO THE ABOVE ADDRESS**.
- The data collected for the purpose of this research project cannot be used for any other purpose without the approval of the Bellberry Human Research Ethics Committee. Requests to use this data for other purposes must be made in the form of a formal research proposal.
- All research data, including electronic data is to be stored by the Principal Investigator for 15 years after the research has been completed or after the last contact, whichever is the later. Data must be recorded in a durable and appropriately referenced form and comply with relevant privacy protocols.
- That copies of all completed consent forms and any other data used in this research may be inspected at any time by representatives of the Bellberry Human Research Ethics Committee.
- That a report on the progress of the research will be made to the Bellberry Human Research Ethics Committee on **21-Aug-19** or on completion of the trial (if sooner) and then annually for the duration of the trial. This report is to indicate whether any ethical problems or complications have arisen, particularly side effects of drugs used or any other factor which may result in the investigation not producing any result as distinct from the anticipated result.
- That you will notify the Bellberry Human Research Ethics Committee of any changes that may be required within the research proposal.
- Bellberry Human Research Ethics Committee approval is conditional upon your meeting any statutory obligations that you may have in relation to this project.
- Adverse Event reporting should be reported to the Bellberry Human Research Ethics Committee as per the monitoring guidelines posted on the website www.bellberry.com.au.
- Any extension to the initial approval period is to be requested in an application via the eProtocol system together with the inclusion of a progress report.
- That you will provide a copy of the Sponsor's final report when this becomes available.

Details of Ethics Committee:

It is the process of the Bellberry Human Research Ethics Committee not to disclose personal details of its reviewing members. This Project was considered by a Committee that fulfilled the requirements of the National Statement (2007) section 5.1.29-30. A member listing is available as an attachment in eProtocol. Please note that the Principal Investigator and Co-Investigators are not members of the Bellberry Human Research Ethics Committees and were not involved in the review of this study.

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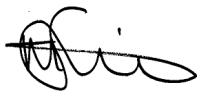
This study has been given the above reference number. Please remember to log on to eProtocol for all further correspondence with the Committee.

Please do not hesitate to contact me if further clarification is required.

Yours sincerely



Mark Slee
Chair, Committee H: (TGA HREC Code: EC00459)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR SIGNATURE DATE