Bellberry Limited supporting research and ethics

129 Glen Osmond Rd
Eastwood SA 5063
Phone: 08 8361 3222
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05-Jul-16

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

Dear Dr. Shakib,
Re: Application No: 2016-03-258
Study Title: CBT124/NHV/001: A randomized, double-blind, single-dose, 3-way, parallel group, comparator-controlled, adaptive design, pharmacokinetic, safety, and tolerability study in healthy male volunteers to evaluate bioequivalence of CBT124 to Avastin® (EU and US)
Application Type: NEW
Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

CBT124NHV001_Cm4116_Pregnant Partner Form_31 March 2016
Cannula Care Participant Info Sheet V1.0 07 Oct 14
CBT124NHV001 (CM4116) Protocol Amendment 1 v2.0_20 May 2016
CBT124NHV001 (CM4116) Protocol Amendment 1 v2.0_20 May 2016_Signature Page_Shakib PI signed
CBT124NHV001_CM4116_PICF_v1.0 26 April 2016
Avastin_EU_Summary of Product Characteristics
Avastin_US_Prescribing Information_20151205
CBT124NHV001_CM4116_IB_V1.0 dated 15 March 2016
CM4116 Print Advertisement V1 13 May 2016
CM4116 Radio Script V1 12 May 2016

Includes:
Insurance Certificate of Currency with expiry of 30 March 2017.

The Committee received a request in relation to consent for sample collection - document "CM4116 Letter to Bellberry_Re Sample Collection and Consent_16 May 2016". The HREC Chair has agreed that, consistent with the reasoning in previous correspondence in 2007, there does not need to be any prior form of consent for the collection/transport of the stool sample required for screening.

The Committee noted that a copy of the eCTN, Cipla CBT124-NHV-001_master eCTN_CT-2016-CTN-01780-1 v1, had been received with the ethics application.

Date of Meeting: 20-Apr-16
Date of Approval: 05-Jul-16
Period of Approval: 05-Jul-16 - 31-Dec-17

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.

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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 **05-Jul-17** 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.

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

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Brian Stoffell
Chair, Committee A (TGA HREC Code: EC00372)
BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR SIGNATURE DATE