

04-Dec-18

Dr. Nicholas Farinola
CMAX
Level 5, 18a North Terrace
Adelaide SA 5000

Dear Dr. Farinola

Re: Application No: 2018-03-196-A-4

Study Title: KD-382-001: A Phase I Randomized, Placebo Controlled, Double Blind, Ascending-Dose And Single Center Study To Evaluate Immunogenicity And Safety Of A Live Attenuated Tetravalent Dengue Vaccine (KD 382) In Flavivirus Antibody Naïve Healthy Adults

Type of Application: Amendment/Investigator Brochure Form

Name of the Documents Submitted and Approved:

Attachments

- 228634 KD-382-001 Protocol 4.0 20181120
- 228634 KD-382-001 Protocol 4.0 20181120 signed PI signature page
- 228634_IB_20181109_V_2.0
- 228634_IB_20181109_V_2.0_Addendum

Includes:

The Committee approved the following document:

- KD-382-001 (CM9118) Subject Diary Vol2 v2.0, dated 16 July 2018.

The Committee noted that this document was a re-named version of that approved in letter dated 30 July 2018, named "KD-382-001 (CM9118) Subject Diary Vol2 v2.0, dated 17 July 2018". The content of this document had not changed, only the document name.

The Committee also noted the following changes to Personnel Information:

- removal of Phoebe Dunsmuir, Tamara Baillie, and Brett Goodsall as Co-Investigators,
- removal of Kelly Harris, Teo Franic, and Mignionne Fernandes as Nominated Contacts,
- addition of Samantha Smith, Briohny Johnston, and Rhys Hamson as Nominated Contacts, and
- revision of email addresses for the Co-Investigators.

Date of Approval: 04-Dec-18

Thank you for submitting the above mentioned application.

The Bellberry Human Research Ethics committee (HREC) has scientifically and ethically reviewed this study.

This Bellberry HREC is constituted and operates 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).

I wish to advise that the Bellberry Human Research Ethics Committee has ethically approved these documents/changes.

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. 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.

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

Yours sincerely



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

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