

05-Nov-18

Professor Adam Guastella
Brain and Mind Centre
100 Mallett Street
Camperdown NSW 2050

Dear Professor Guastella,

Re: Application No: 2018-05-322

Study Title: AXL-1224-2004-001: A Two-Arm, Single Sequence, Multiple Ascending Dose Study of the Safety and Tolerability of AB-1224 and AB-2004 in Young Adult & Pediatric Autism Spectrum Disorder Populations

Application Type: NEW

Type of Review: FULLBOARD

Name of the Documents Submitted & Approved: Attachments

AXL-1224-2004-001_Protocol_Version 2.0_Amend #1_22Jun2018
AXL-1224-2004-001_V 2.0_Amend #1_Summary of Changes_22Jun2018
AXL-1224-2004-001_Sample eDiary_AXL_V1 Dated 08May2018
AXL-1224-2004-001_Participant Identification Card_V1 Dated 08May2018
AXL-1224-2004-001_PIS-CF (12-17 Years)_AU_Master_V2_27June2018
AXL-1224-2004-001_PIS-CF_Cohort 1_Parent Guardian_AU_Master_V2_28June2018
AXL-1224-2004-001_PIS-CF_Cohort 2_AU_Master_V2_27June2018
AXL-1224-2004-001_PIS-CF_Cohort 3 4_Parent Guardian_AU_Master_V2_6June2018
AXL-1224-2004-001_PIS-CF_Cohort 1_Parent Guardian_AU_Master_V3_6Aug2018
AXL-1224-2004-001_IB_AB-1224_V.4.0_02May2018
AXL-1224-2004-001_IB_AB-2004_V1.0_05Apr2018
AXL-1224-2004-001_6-GSI_AXL_V1 dated 08May2018
AXL-1224-2004-001_GSRS Interview_AXL_Version 1 dated 08May2018
Child & Adolescent Symptom Inventory-5_CASI 5_2013
Childhood Autism Rating Scale 2nd Ed _CARS2 HF_W-472B_2010
Childhood Autism Rating Scale 2nd Ed_CARS2 ST_W-472A_2010
Questionnaire for Parents and Caregivers_CARS2 QPC_W-472C_2010
Repetitive Behavior Scale_AXL V1 Dated 08May2018
SRS-2 Adult_W-608D_2012
SRS-2 school age_W-608A_2012
Childrens Anxiety Rating Scale (PARS)_Version 1.2_11 July 1997
ABC score sheet_Copyright 2017 Michael Aman PhD
AXL-1224-2004-001_Explanation of study scales_10May2018
Follow-Up Dietary Questionnaire_Version #1_25Jun2018
Screening Dietary Questionnaire_Version #1_25Jun2018
Vineland-3 Comprehensive Interview Form_Product Number 31321

ABC- Community_Copyright 2017 Michael Amand PhD
ADOS-2 Questionnaires_ADOS-2 Module 1
ADOS-2 Questionnaires_ADOS-2 Module 2
ADOS-2 Questionnaires_ADOS-2 Module 3
ADOS-2 Questionnaires_ADOS-2 Module 4

Includes:

- AXL-1224-2004-001_PSP_signed 28June2018
- AXL-1224-2004-001_Certificate of Insurance_16May2018
- AXL-1224-2004-001_Site Approval Form 27Jul2018

CONDITIONAL APPROVAL: **The approval for this study is conditional upon receipt of the fully executed Standard Indemnity. The study must not commence until this document has been provided. Please submit the fully executed Standard Indemnity on an amendment form when available.

Date of Meeting: 23-May-18

Date of Approval: 01-Nov-18

Period of Approval: 01-Nov-18 - 01-Nov-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 **01-Nov-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.

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

Michael James

Michael James

Chair, Committee C: (TGA HREC Code: EC00430)

BELLBERRY HUMAN RESEARCH ETHICS COMMITTEE

PRINCIPAL INVESTIGATOR SIGNATURE DATE