Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 21/CEN/203

28 October 2021

Dr Swee Tan

PO Box 7184 ,Newtown
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New Zealand

Tēnā koe Dr Tan

APPROVAL OF APPLICATION

Study title: Targeting the Renin-Angiotensin System in Glioblastoma (TRAS-GB) Trial

I am pleased to advise that your application was **approved** by the Central Health and Disability Ethics Committee (the Committee). This decision was made through the RMDF pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Central Health and Disability Ethics Committee is required.

Standard conditions:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 10 September 2022.

As your study is an intervention study involving a new medicine, all progress reports **must** be accompanied by an annual safety report. While there is no prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include a brief description and analysis of:

- new and relevant findings that may have a significant impact on the safety of participants
- the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- any measures taken or proposed to minimise risks. (Where such a proposed measure would be a substantial amendment, it must be submitted for HDEC review in the normal way).

For the avoidance of doubt, Development Safety Update Reports may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should be accompanied by comment from the New Zealand coordinating investigator of the study.

Please refer to paragraphs 206 to 208 of the *SOPs* for further information.

Participant access to compensation

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will notbe eligible for publicly-funded compensation through the Accident Compensation Corporation. Further information and assistance.

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Covering Letter	includes summary of changes	27/07/2021	Covering Letter (1)
CV for Coordinating Investigator	Dr Swee Tan CV	27/07/2021	CV for CI (1)
Evidence of Scientific Review	SCOTT approval letter Protocol version 1, dated 1 June 2021	27/07/2021	Evidence of scientific review (1)
Protocol	includes EORTC QLQ-C30 and QLQ-BN20 questionnaires in Appendices 1 & 2	27/07/2021	Protocol (1)
Other	Maori consultation email documentation	27/07/2021	Other (1)
PIS/CF	Main PIS/CF	27/07/2021	PIS/CF (1)
PIS/CF	PIS/CF for optional tissue (blood samples)	27/07/2021	PIS/CF (1)
PIS/CF	PIS/CF for photographic and radiographic records	27/07/2021	PIS/CF (1)
Other	EORTC QLQ-C30	27/07/2021	Survey/questionnaire (3)
Other	EORTC QLQ-BN20	27/07/2021	Survey/questionnaire (1)
MDF Doc	Form Submission	04/08/2021	NZ/1/D9EA112
Other	HDEC Letter 21CEN203 Valid HDEC Application.pdf	17/08/2021	HDEC Documents

Review Document Type	Review Document File Name	Review Document Version Date
RED Members Portal Comments	Member_Portal_Comments.doc	29/08/2021
Response to PA Document	HDEC_Cover Letter_Response to provisional approval_24 Sept 2021.pdf	24/09/2021
Response to PA Document	Phase II GB_ Data Management Plan_22 Sept 2021.pdf	22/09/2021
Response to PA Document	Phase 2 GB Study Main Consent_23 Sept 2021_clean.pdf	23/09/2021
Response to PA Document	Phase 2 GB Study Main Consent_23 Sept 2021_tracked.pdf	23/09/2021
Response to PA Document	Phase 2 GB Optional Blood Sample Consent_23 Sept 2021_clean.pdf	23/09/2021
Response to PA Document	Phase 2 GB Optional Blood Sample Consent_23 Sept 2021_tracked.pdf	23/09/2021