Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 FULL 18838

16 November 2023

Dr Paul Hamilton

Level 2, 2 Fred Thomas Drive
Takapuna
Auckland
0622
New Zealand

Tēnā koe Dr Hamilton

APPROVAL OF APPLICATION

Study title: BP16-101: A Randomized, Double-Blind, Parallel group, Comparative Phase I study for the assessment of Pharmacokinetics, Pharmacodynamics, Safety, tolerability and Immunogenicity of BP16 (Denosumab) versus US licensed - Prolia® and EU approved - Prolia® Following a Single dose (60mg/mL) Subcutaneous Administration in Healthy Male Volunteers

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee). This decision was made through the FULL 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 Northern A 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 16 November 2024.

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 **not** be 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, as well as our General FAQ and Ethics RM user manual.

Nāku noa, nā

Ms Catherine Garvey

Chair

Northern A Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Evidence of Sponsor Insurance	CPBL- BP16-101 - Certificate - Australia_dated 05DEC2022	05/12/2022	EXP 31DEC2023
Evidence of CI Indemnity	Paul Hamilton Indemnity Insurance 14DEC22-14DEC2023	21/12/2022	14DEC2022-14DEC2023
Investigator's Brochure	BP16_Investigator Brochure_V2.0_03Jul2023	03/07/2023	V2.0
Protocol	BP16-101_Phase 1 Study Protocol V3.0_13Jul2023	13/07/2023	V3.0
Non-Review Document	PCRN Study Participant Card V2 dated 13SEP2023	13/09/2023	V2
CV for Coordinating Investigator	Paul Hamilton CV 18Sep2023	18/09/2023	N/A
Scientific Peer Review	BP16-001_NZ_PCRN_Peer Review Letter_18Sep2023	18/09/2023	N/A
PIS/CF	BP16-101 NZ Main PICF V1 dated 21Sep2023	21/09/2023	V1
PIS/CF	BP16-101 NZ Optional PICF V1 dated 21Sep2023	21/09/2023	V1
Data and Tissue Management Plan	BP16-101 Data Tissue Management Plan V1 dated 21Sep2023	21/09/2023	V1
Advertisement	BP16-101 HDEC Submission PCRN Advertising Material V2 26Sep2023	26/09/2023	V2
Response to PA Document	BP16-101_New Zealand_Insurance Certificate_06Oct2023	06/10/2023	06OCT2023-05OCT2024
Response to PA Document	BP16-101_NZ_Medsafe Initial Approval_19Oct2023	19/10/2023	N/A
Response to PA Document	BP16-101 NZ Optional PICF V1 dated 25Oct2023 tracked	25/10/2023	V1 tracked
Response to PA Document	BP16-101 NZ Optional PICF V1 dated 25Oct2023 clean	25/10/2023	V1
Response to PA Document	BP16-101 HDEC Submission PCRN Advertising Material V3 25Oct2023 tracked	25/10/2023	V3 tracked
Response to PA Document	BP16-101 HDEC Submission PCRN Advertising Material V3 25Oct2023 clean	25/10/2023	V3
Response to PA Document	BP16-101 NZ Main PICF V1 dated 27Oct2023 tracked	27/10/2023	V1 tracked
Response to PA Document	BP16-101 NZ Main PICF V1 dated 27Oct2023 clean	27/10/2023	V1
Response to PA Document	BP16-101 HDEC Cover Letter dated 30OCT2023	30/10/2023	N/A

Review Document Type	Review Document File Name	Review Document Version Date

Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Catherine Garvey (Lay (the law)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Dr Leonie Walker (Lay (ethical/moral reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)), Dr Andrea Forde (Non-lay (intervention studies)), Mr Derek Chang (Non-lay (intervention studies)).

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference).

http://www.ethics.health.govt.nz