NZRGM Vol 3, August 1998

APPLICATION FOR APPROVAL OF A CLINICAL TRIAL

Medicines Act 1981, section 30

TITLE OF PROPOSED TRIAL: A Phase I/II, Open Label, Single Centre Study to Evaluate the Safety, Reactogenicity and Immunogenicity of Three Doses of MeNZB NZ OMV when Administered to Healthy Adults, Laboratory Workers at ESR. (Sponsor format code: V60P4)

STUDY PHASE OF TRIAL: Phase I/II

MEDICINE:

Chemical Name: Outer Membrane Vesicle (OMV) Vaccine derived from *Neisseria meningitidis* strain NZ98/254

Non Proprietary Name: Not applicable

Trade name: MeNZB™

Use(s): Active immunisation for the prevention of invasive disease caused by Neisseria Meningitis serogroup B (New Zealand specific strain classified as subtype B 4: P1.7b,4)

APPLICANT:

Name: Chiron S.r.l.

Address: Via Fiorentina, 1 – 53100 Siena, Italy
Phone +39 0577 243111; Fax +39 0577 243074

Representative applicant:

Name: Multichem NZ Ltd

Phone Number: +64 9 441 3220

Fax Number: +64 9 441 2596

Designation:

PROPOSED CLINICAL INVESTIGATORS:
(If more than two, please indicate on the reverse of this page)

a) Name: Stewart Reid, MD

b) Position: Member Vaccine sub-committee Medicines Assessment Advisory Committee, Ministry of Health

Curriculum Vitae attached **(Attachment A to this application form)** Yes ☒ No ☐

Signed consent of the investigator to undertake the trial attached Yes ☒ No ☐

Sponsor Agreement is included as page 41 of the Clinical Study Protocol (Attachment II to cover letter)

THE UNIVERSITY OF AUCKLAND

The ESR Adult Meningococcal B Vaccine Study

A Phase I/II, Open Label, Single-Centre Study to evaluate the Safety, Reactogenicity, and Immunogenicity of Three Doses of NZ MenB OMV when Administered to Healthy Adults, Laboratory Workers at ESR.
(Sponsor Code: V60P4)

Principal Investigator:
Dr Stewart Reid, 82 Owen Street, Lower Hutt. Tel: 021 650 807
Sub-Investigators:
Dr Sharon Wong, 17 Lambie Drive, Manukau City. Tel: (09) 263 3994.
Dr Chris Masters, Ropata Medical Centre, 577 High Street, Lower Hutt. Tel: (04) 920 0800.

Introduction

You are invited to take part in a research study designed to evaluate a vaccine that may provide protection against the strain of meningococcal serogroup B disease prevalent in New Zealand. Before you give your consent to participate you must read this information sheet, which explains the reason for doing this study, what happens during it, and the risks and benefits of participating in this study. As you read it, you might like to underline any areas of which you are unsure. When you have read it carefully, please ask any questions necessary for you to understand what participation in this study will involve.

Purpose

New Zealand is now in its 12th year of a meningococcal epidemic, caused by the bacteria *Neisseria meningitidis* (meningococcus). Meningococcus is highly contagious and can lead to rapid infection resulting in meningitis and/or bacteraemia (bugs in the blood). It is usually spread from a carrier with no symptoms of the disease. More rarely, it is spread from another person who has the disease. Infants and young children are the main groups at risk although it does occur in adolescents and adults.

Complications arising from meningococcal infection are numerous and include death or serious disability, such as loss of limbs and neurological abnormalities. Early treatment of the disease with antibiotics may improve the chances of recovery and limit complications. Primary intervention by vaccination is potentially the most effective management for infectious disease epidemic control.

The bacteria causing meningococcal disease can belong to one of several different serogroups; serogroup B is the cause of the current epidemic. A 'candidate' vaccine, specifically tailored to combat the outbreak strain in New Zealand (NZ MenB OMV), is very similar to a 'parent' vaccine (MenBvac), produced in Norway (by the Norwegian Institute of Public Health, NIPH) which was developed using their own outbreak strain. The parent vaccine was administered to 120,000 people in clinical trials in Norway. In New Zealand, two evaluation studies comparing MenBvac and NZ MenB OMV have been completed; one involved 73 healthy adults in Auckland, the other involved 300 children aged 8-12 years in South Auckland. Another two studies are currently underway in South Auckland, one involving 300 toddlers aged 16-24 months that commenced in February 2003, and a second involving 300 infants aged 6-8 months that commenced in May 2003. The vaccine used in these studies was produced by NIPH in Norway. The rationale for the current study is to evaluate the safety and immunogenicity of the NZ MenB OMV vaccine produced at Chiron Vaccines in Siena.

Laboratory workers at ESR working with the meningococcal isolates responsible for the current epidemic are at great occupational risk (estimated at 500 times greater than persons of an equivalent age) to contract meningococcal disease. ESR has agreed to give their employees, involved in the meningococcal testing procedures, the opportunity to participate in this trial as it may provide them with some protection from disease caused by group B meningococcus.

Organisation of the study

This study is being organised and managed by The University of Auckland. It is sponsored by Chiron S.r.l., Siena, Italy in partnership with the New Zealand Ministry of Health. The vaccine used in this trial has been manufactured by Chiron S.r.l.

How does the study work?