NEWS RELEASE
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GROPEP STARTS PHASE 1 INFERTILITY TRIAL

GroPep's program - to develop a treatment for a condition that potentially causes 50% of all miscarriages - reached a major milestone today with commencement of recruitment of healthy women volunteers into a Phase 1 trial of its infertility drug, PV903.

The drug is targeted to treat recurrent miscarriages caused by an abnormal immune response to the foetus – a condition for which there is no current treatment.

The market for a drug to treat this condition is estimated to be up to US$750 million annually.

Listed biopharmaceutical company GroPep Limited (ASX:GRO) announced today that it will commence a Phase 1 trial of its infertility drug PV903.

The trial, which will be conducted under the Therapeutic Goods Administration Clinical Trial Notification scheme, was approved by the Royal Adelaide Hospital Research Ethics Committee.

Recruitment will begin immediately to allow medical screening and enrolment of the first cohort of subjects in mid-February 2006. The results of the trial should be known in late 2006, depending on recruitment rate.

The trial, conducted at the CMAX Adelaide-based facilities, involves healthy female volunteers each receiving a single administration of PV903 gel (or placebo) as they are enrolled sequentially into three groups with the PV903 dose escalating between groups. A total of 36 volunteers will complete the trial.

The objectives of the trial are to evaluate the safety and tolerability of vaginally administered PV903 gel, and to determine whether PV903 has effects on vaginal immune cells in a manner consistent with its proposed role in treating immune-based infertility.

Over 50% of miscarriages have no apparent explanation and some scientists believe that women who suffer from repeated miscarriage have an immune system that attacks the embryo as "foreign". PV903 is a recombinant version of a protein that is naturally found in semen and thought to be responsible for instructing the mother's immune system to tolerate the implanting embryo.

Preclinical studies previously reported by GroPep have shown that a single intravaginal dose of PV903 halves the miscarriage rate in a mouse model of reproductive failure that shares many features with recurrent miscarriage in humans. A Clinical Research Study conducted in the last six months has enabled GroPep to identify and measure a range of immune cells from the cervix of

healthy women volunteers. Changes in these cells after the introduction of PV903 are expected to indicate whether the treatment is effective.

GroPep CEO Mr Bob Finder said he was delighted at the commencement of the PV903 clinical trial. He further noted, "This trial represents the culmination of several years work by GroPep and our collaborators to understand the role of PV903 in immune-based infertility, undertake toxicology studies and develop a stable gel-based formulation."

"As this is a potential first-in-class product, GroPep has had to develop new methods to measure the effect of PV903 on the immune system. We are now in a position to initiate the clinical phase of this program, which has the potential to offer the first drug treatment for recurrent miscarriage", Mr Finder added.

The following information is provided regarding the trial.

Name of Trial
A Phase Ia, randomised, double-blind, placebo-controlled, sequential single-dose escalating trial in healthy adult female volunteers to evaluate the short-term safety, tolerability and preliminary immune activity of vaginally administered PV903 gel.

Objectives
Primary objectives

To evaluate the short-term systemic and local safety and tolerability of PV903 gel by measuring endpoints such as treatment emergent adverse events, including colposcopy examination findings, clinical laboratory abnormalities and assessment of the generation of serum antibodies to PV903 following vaginal administration of a single 3mL volume on one occasion.

Secondary objectives

To evaluate preliminary immune activity of PV903 gel in the treatment of recurrent miscarriage by determining the nature of any changes in local cervical immune cell populations or cytokine levels in response to vaginal PV903. Populations of immune cells will be assessed using flow cytometry.

To measure systemic drug levels and assess the pharmacokinetics of PV903 following administration of the highest dose.

Products
The trial investigational drug products are a gel containing recombinant human transforming growth factor-β3 (*rh*TGF-β3, code-named PV903), at three concentrations (0.5μg PV903/mL, 4.0μg PV903/mL and 20μg PV903/mL) and a placebo gel. The batch *rh*TGF-β3 was manufactured in compliance with the code of Good Manufacturing Practice (GMP). These drug products will be administered to the vagina as 3mL doses of gel using a pre-loaded applicator.

Subjects
Trial subjects will be adult female volunteers aged 18 to 45 years who are currently taking an oral contraceptive pill. The women will be non-

institutionalised volunteers comprised of members of the community at large. Sufficient women volunteers will be screened to recruit 36 subjects into the trial.

Design
The trial will be conducted according to GroPep Clinical Trial Protocol No: CT-008-05. This is a double-blind, placebo-controlled, randomised, Phase Ia study performed in healthy adult female volunteers (three groups of 12 subjects) at a single centre with three pre-determined PV903 dose levels. Women deemed eligible to participate will be enrolled consecutively into Groups 1 through to 3 (i.e., Low, Mid and High PV903 dose levels). Within each dosing group, the 12 subjects will be randomly assigned such that 9 of the 12 subjects will receive a single dose of active PV903 gel drug product and 3 of the 12 subjects will receive placebo (gel alone).

Location
The trial will be conducted at the CMAX (A Division of Institute of Drug Technology Australia Limited) facilities based in North Adelaide and the Royal Adelaide Hosptial.

Trial Standard
This study will be conducted in accordance with the Principles of the International Conference on Harmonisation Note for Guidance on Good Clinical Practice (ICH GCP; as adopted in Australia, July 2000) which build upon the ethical codes contained in the Declaration of Helsinki and the Australian National Statement on ethical Conduct in Research Involving Humans (1999) and the National Health and Medical Research Council Statement on Human Experimentation and Supplementary Notes 5 and 7 issued in October 1983 and November 1992, respectively

Timeline for completion
The expected duration of each individual subject's trial participation will be 37 days. Allowing for a thorough analysis of the safety data generated by each cohort prior to dose-escalation, the results of the trial should be known in late 2006, depending on the recruitment rate.

What is Recurrent Miscarriage?

A considerable proportion of cases of recurrent miscarriage occur in couples where the mother develops an adverse immune response to the father's antigens present on the foetal placenta. It is estimated that, in the United States alone, there are 170,000 women who seek treatment for this traumatic condition every year. GroPep's product, PV903, is a recombinant version of a protein, which is naturally found in semen. It is thought that this protein is responsible for instructing the mother's immune system to tolerate the implanting embryo, rather than identifying it as a foreign object and subsequently rejecting it.

Commercialisation

Market research commissioned by GroPep has indicated that, if successful, sales of up to US$750 million per annum are possible for this product. GroPep's commercial strategy is to seek a partnership with a larger pharmaceutical or biotechnology company at the conclusion of the Phase 1 trial, preferably with an established franchise in reproductive medicine, to develop the product through further clinical trials and market launch in return for upfront and milestone fees and royalty payments.

About GroPep

GroPep is a world leader in the development, manufacture and commercialisation of biologically active proteins for cell culture and biomedical research. The Company has an active biopharmaceutical development program that establishes proof-of-concept for products in humans and partners the later stages of development and marketing with major pharmaceutical companies. GroPep is listed on the Australian Stock Exchange (ASX: GRO).

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