NEWS RELEASE
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GROPEP COMPLETES PHASE 1a 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 completion of a Phase 1 trial of its infertility drug, PV903.

The drug is targeted to treat recurrent miscarriage 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.

GroPep Limited (ASX: GRO) has today announced completion of the Phase 1a trial of its infertility drug PV903. The trial met its primary objective in demonstrating that vaginally administered PV903 gel is safe and well tolerated. The trial did not meet one of its secondary objectives, as there was no change in vaginal immune cell populations or cytokine levels when comparing treatment to placebo gel alone. The other secondary objective was achieved, showing that systemic PV903 was not detected following a single intravaginal administration of PV903 gel.

The trial was conducted at the CMAX Adelaide-based facilities under the Therapeutic Goods Administration Clinical Trial Notification scheme. Thirty-six healthy female volunteers (aged from 18 to 41) each received a single administration of PV903 gel or placebo. Subjects were enrolled sequentially into three groups of 12, with the dose of PV903 gel escalating between groups.

Assessment of treatment emergent adverse events, including colposcopic examination findings and clinical laboratory abnormalities showed PV903 gel to be safe and well tolerated by all subjects. No antibodies to PV903 were detected in the blood of trial subjects.

A comprehensive assessment of vaginal immune cell populations following treatment with the doses of PV903 gel revealed no change in the number or proportion of different classes of immune cells when compared to treatment with placebo gel alone.

Recent preclinical studies have demonstrated immune cell recruitment to the vagina in animal studies after intravaginal administration of PV903 using a gel formulation identical to that used in the human Phase 1a trial. These data build on preclinical studies previously reported by GroPep where a single intravaginal dose of PV903 was shown to halve the miscarriage rate in a mouse model of reproductive failure, and demonstrate that PV903 affects immune cell populations in a manner consistent with induction of immune tolerance to a subsequent pregnancy.

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The future of the project will be assessed based on a review of the data with potential licensing partners and in light of the recent announcement that GroPep and Novozymes A/S have reached an agreement under which Novozymes will acquire all of the issued securities in GroPep via Schemes of Arrangement between GroPep and its share and option holders. This transaction is expected to be completed by the end of 2006, subject to satisfying all relevant conditions (GroPep News Release dated 14 August 2006).

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.

Investigational drug products
The trial investigational drug products were gel-based formulations of 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. These drug products were administered to the vagina as 3mL doses of gel using a pre-loaded applicator.

Trial Design and Subjects
The trial was 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 (GroPep Clinical Trial Protocol No: CT-008-05).

Trial subjects were adult female volunteers aged 18 to 41 years who were taking an oral contraceptive pill. Of the 58 female volunteers screened to determine eligibility to participate in the trial, 36 were randomised and treated. Eligible females were enrolled consecutively into three dosing groups (i.e., Low, Mid and High PV903 dose levels). Within each dosing group, the 12 subjects were randomly assigned such that 9 of the 12 subjects received a single dose of active PV903 gel drug product and 3 of the 12 subjects received placebo (gel alone). There were no dropouts with all subjects randomised to treatment with PV903 gel or placebo gel completing all required procedures and assessments for the study.

The **Primary Objective** was 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.

PV903 gel was shown to be safe and well tolerated. Treatment-emergent adverse events were experienced by 20 of the 36 subjects. Of these 20 subjects, 4 were in the low-dose group, 5 in the mid-dose group, 6 in the high-dose group and 5 in the placebo-treated group. The relationship between the adverse event to the investigational product was rated by the

Investigator as “probable” in one instance (excess of normal vaginal discharge on the day after treatment experienced by a subject receiving the placebo gel). Adverse events deemed possibly related to treatment were experienced by 13 subjects, with the remainder of the adverse events rated as “remotely” or “unrelated” to treatment. Two subjects experienced adverse events that were classified as being of “moderate” intensity, with all other adverse event rated as “mild” in intensity. All adverse events in the mid- and high-dose groups were rated as “mild”. There were no serious adverse events or adverse events associated with withdrawal from the study.

No subjects generated an antibody response to the single vaginal administration of PV903 gel.

The **Secondary Objectives** were to (i) 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, and (ii) to measure systemic drug levels and assess the pharmacokinetics of PV903 following administration of the highest dose.

Populations of immune cells were assessed using flow cytometric analysis of samples collected by endocervical cytobrush and vaginal lavage procedures 44 hours after dosing with PV903 or placebo gel. Antibody markers to classes of leukocytes (granulocytes, macrophages, lymphocytes and natural killer cells) were used to characterise any immune cell response to vaginal PV903. When compared to the placebo gel-treated group, no significant change in the number or proportion of vaginal immune cell populations was seen after treatment with any of the doses of PV903 gel.

With the exception of one subject who exhibited background levels of circulating TGF-β3 prior to dosing, no TGF-β3 was detected in serum samples after intravaginal administration of PV903 gel.

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 product development and marketing with major pharmaceutical companies. GroPep is listed on the Australian Stock Exchange Limited (ASX code: GRO).

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