



ASX Announcement

17th July 2006

First patients complete BDM-E phase II study

Australian biopharmaceutical development company BioDiem Ltd (ASX:BDM) said today the first patients in the phase I/II clinical trial for its peptide BDM-E had completed treatment and follow up assessments.

The BDM-E Phase I/II trial is a double-blind, placebo controlled study of the efficacy of BDM-E in the treatment of diabetic macula oedema, a leading cause of blindness.

Although the efficacy results will not be known until the trial is complete and the data is unblinded, no patient enrolled into the trial to date had experienced any adverse effects attributed to the study treatment. Only 1 patient has left the study, while the first 15 patients have completed the study, which involved 10 days treatment with BDM-E and follow up safety and efficacy assessments at days 17, 40 and 100.

CEO of BioDiem, Mr Tom Williams said: "There are currently no approved drugs for treating diabetic retinopathy and although steroids are being used off label, they are often associated with serious adverse consequences like cataracts and glaucoma. So it's important to see that BDM-E is so far getting a clean bill of health with no serious adverse events in this trial."

The recruitment of patients into the Phase I/II clinical trial has taken more time than initially anticipated and BioDiem is working closely with the Swiss Contract Research Organisation supervising the trial and a number of strategies are being employed to speed enrolment and boost the progress of the clinical trial. BioDiem has recently received regulatory approval for additional clinical sites to expedite recruitment.

Mr Williams commented: "It's important to maintain the very strict entry criteria for patients that has principally lead to an extension of recruitment time. If BDM-E can demonstrate that it can improve the vision of these patients and retain its apparent safety profile it will represent an important advance in treatment for this sight threatening condition."

The objective of this clinical trial will be to demonstrate the safety, tolerability, and efficacy of BDM-E administered by sub-cutaneous injections, in comparison with placebo, in patients with clinically relevant diabetic macular oedema. The study end-points will be (a) changes in macular oedema measured by ocular coherence tomography and (b) changes in visual acuity measured over a 3 month observation period. BioDiem is aiming to complete enrolment in the first quarter of January 2007 and report the results in mid 2007.

Diabetic retinopathy is a complication of diabetes causing damage to blood vessels in the retina. It is the leading cause of blindness in working age people.

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