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ASX Announcement

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BioDiem announces Clinical Trial in Diabetic Eye Disease

Australian biopharmaceutical development company BioDiem Ltd (ASX:BDM) announced today it has received regulatory approval to commence a phase I/II clinical trial for its peptide BDM-E in patients with diabetic macula oedema, a leading cause of blindness.

BDM-E is a potential treatment for the two major causes of blindness - Diabetic Retinopathy (DR) and Age-related Macular Degeneration (AMD). It is a small synthetic peptide which *in vitro* studies show stimulates growth of new retinal pigmented epithelial cells and inhibits the growth of choroidal endothelial cells associated with unwanted neovascularisation.

BioDiem CEO Tom Williams said: "The trial will test the ability of BDM-E to reduce the swelling that's typical of diabetic retinopathy in the back of the eye, which often leads to significant vision loss.

"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."

Associate Professor Mark Gillies of Sydney University, who designed the trial, said: "There is an urgent need for new safe and effective treatments for diabetic retinopathy and other retinal diseases such as age related macular degeneration. Nearly all patients who have Type 1 diabetes for 20 years or more will have evidence of diabetic retinopathy. Up to 21% of people with Type 2 diabetes have retinopathy when they are first diagnosed with diabetes, and most will eventually develop some degree of retinopathy. Diabetes is responsible for 8% of legal blindness, making it the leading cause of new cases of blindness in adults 20-74 years of age. In the United States, each year, 12,000 to 24,000 people lose their sight because of diabetes."

Diabetic retinopathy is a term used for the abnormalities of the small blood vessels of the retina caused by diabetes, such as weakening of blood vessel walls or leakage from blood vessels.

Study Design: The study will include 192 patients at 8 centres in St. Petersburg and Moscow in Russia. The trial will be managed by a Swiss contract research organisation specialising in running clinical eye studies to best international standards. The first patients are expected to be treated in January 2006 and the results should be available by late 2006. 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. The trial will be a placebo controlled, randomised double-blinded Phase I/II trial designed to establish proof of concept. The study will be conducted in compliance with ICH Good Clinical Practice (GCP) guidelines as required by the world's leading regulatory authorities, including the FDA, EMEA and TGA.
BioDiem takes an international collaborative approach to developing its products in a cost effective manner. Mr Williams said "We contract the work out to different organizations in Australia or overseas depending on their ability to perform. In this case, where clinical trial material must be made to GMP standards, the raw material is being synthesised in California and the final clinical trial ampoules made in Germany."

Only two drug treatments are currently available for AMD, but these are effective in only a small percentage of patients. Nonetheless, sales of up to US$1 billion are projected by 2008. There is currently no approved drug treatment for DR. Intra-ocular steroids have been used with some success, but their use is limited by major side effects such as cataract and glaucoma. A safe and effective drug treatment for DR would be expected to have major commercial potential, especially if it did not have to be given by intra-ocular injection.

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