BioDiem Ltd
ABN 20 096 845 993
Phone: +61 3 9613 4100 Fax: +61 3 9613 4111
Level 10, South Tower, 459 Collins Street, Melbourne Victoria 3000
Email: info@biodiem.com Web: www.biodiem.com

ASX Announcement

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BioDiem commences clinical trial for diabetic eye disease

Australian biopharmaceutical development company BioDiem Ltd (ASX:BDM) announced today it has commenced recruitment for a phase I/II clinical trial of 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 have shown stimulates growth of new retinal pigmented epithelial cells and inhibits the growth of choroidal endothelial cells associated with unwanted neovascularisation.

Commenting on the trial today, BioDiem Chief Executive Officer, Tom Williams said, "The need for an effective treatment for diabetic retinopathy is being driven by an increased prevalence of diabetes. Vision impairment is a common complication of both Type 1 and Type 2 diabetes, with most patients with Type 2 diabetes eventually developing some degree of retinopathy. When someone is diagnosed with diabetes their risk of blindness is increased 25 times. This trial is aimed at developing an effective and safe treatment to fill the need that exists in this market".

The proof of concept trial will test the ability of BDM-E to reduce the swelling in the back of the eye which often leads to significant vision loss. The study end-points are (i) changes in macular oedema measured by ocular coherence tomography and (ii) changes in visual acuity to be measured over a 3 month observation period.

The trial will include 192 patients at 8 centres in St. Petersburg and Moscow in Russia. The study is being conducted in compliance with ICH Good Clinical Practice (GCP) guidelines and is being managed by a Swiss contract research organisation that specialises in running clinical eye studies. Recruitment is expected to be completed in June with preliminary results available by the end of this year.

About Diabetic Retinopathy and Age-related Macular Degeneration

There is currently no approved treatment available for Diabetic Retinopathy (DR) and only two drugs available for Age-related Macular Degeneration (AMD) and these are effective in only a small percentage of the treatment population. Nonetheless, sales of up to US$1 billion are projected by 2008. Intra-ocular steroids have been used with some success in DR, 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. BDM-E is being given in this trial by subcutaneous injection in a manner familiar to diabetics with their administration of insulin.

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.

Retinopathy progresses from non-proliferative or background retinopathy to proliferative retinopathy. Proliferative retinopathy, the more serious form, occurs when new blood vessels branch out or proliferate in and around the retina. It can cause bleeding into the fluid-filled centre of the eye or swelling of the retina, and lead to blindness.

AMD is the leading cause of blindness in elderly people in the developed world. Archives of Ophthalmology in 2004 estimated that 1.75 million US residents have significant symptoms associated with AMD and that number is expected to grow to almost 3 million by 2020. DR is estimated to affect half of all diabetics during the course of their disease progression, and in 2002 there were 18.2 million Americans with diabetes.

For further information:

Mr. Tom Williams
CEO
BioDiem Ltd
+ 61 3 9613 4100
+ 419 868 911

Mr. Rick Willis
Hinton and Associates
+ 61 3 9600 1979
+ 411 839 344

www.biodiem.com