

BIODIEM LTD

ABN 20 096 845 993

Level 10, South Tower, 459 Collins Street, Melbourne, Victoria, 3000

Australia

Phone: +613 9613 4100 Web: www.biodiem.com

ASX Announcement

BIODIEM PRESENTS FINDINGS AT INTERNATIONAL EYE RESEARCH MEETING

Melbourne, 23 July 2012: Australian infectious disease therapy and vaccine development company BioDiem Ltd (ASX: BDM) today announced positive results from formal studies of its BDM-E eye disease drug, presented over 21 – 22 July at the International Society for Eye Research (ISER) meeting in Berlin, Germany. The ISER convenes leading researchers and clinicians in the area of eye disease.

BDM-E has received Orphan Drug designation from the United States Food & Drug Administration (FDA) for the treatment of the inherited degenerative eye disorder, *retinitis pigmentosa* (RP).

The eye research results presented at the ISER Conference confirm the potential of BDM-E:

- 1) BDM-E was found to reduce formation of abnormal blood vessel growth;
- 2) BDM-E was found to reduce the signs of damage typical to retinitis pigmentosa; and
- 3) BDM-E was shown to improve the function of the retina and inhibit the death of cells imperative for sight.

BioDiem recently signed a research agreement with the Foundation Fighting Blindness, a leading US eye research advocate, to test BDM-E in a pre-clinical model of RP, a genetic cause of blindness without effective treatment options.

The Australian research into BDM-E being presented in Berlin was conducted under retinal disease specialist Professor Jennifer Wilkinson-Berka from Monash University, a Senior Research Fellow of the National Health and Medical Research Council (NHMRC) of Australia, and Associate Professor Erica Fletcher from The University of Melbourne.

The encouraging results add further momentum to BioDiem's plan to outlicense the BDM-E technology. "These results contribute to the strong and growing preclinical evidence showing BDM-E's positive effect in models of eye disease, and will help progress outlicensing opportunities for the drug." said BioDiem Chief Executive Officer Julie Phillips.

The scientific poster demonstrating the results of the BDM-E studies may be found at www.biodiem.com.

ENDS

About BioDiem Ltd

BioDiem is an ASX-listed company based in Melbourne with an international focus on discovering, developing and commercialising world-class research and technology targeting cancers and infectious diseases. BioDiem's core technologies include the Live Attenuated Influenza Virus (LAIV), the SAVINE platform and the BDM-I antimicrobial compound.

The LAIV influenza vaccine is an intranasal vaccine to prevent infection from seasonal and pandemic influenza. The LAIV influenza vaccine can be produced using both egg-based and cell-based manufacturing methods. The cell-based LAIV vaccine has completed a Phase II clinical trial in Europe. The egg-based LAIV vaccine technology is licensed to the World Health Organization as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply.

The LAIV influenza vaccine is marketed as Nasovac™ in India by the Serum Institute of India, and has been licensed to China-based Changchun BCHT Biotechnology Co. The LAIV vaccine was in-licensed from the Institute of Experimental Medicine in St Petersburg, Russia where it has been used for over a decade in many millions of people - children, adults and the elderly. The LAIV is administered by nasal spray and induces a rapid immune response in the mucosal lining of the nose and pharynx.

The LAIV is also being developed as a viral vector for making novel non-influenza vaccines for different diseases including cancers. Viruses have the ability to generate proteins prolifically and can be programmed to produce disease-specific proteins. As part of a vaccine, disease-specific proteins can help generate a beneficial immune response.

SAVINE (patented Scrambled Antigen Vaccine) is a platform technology for the design of antigens for incorporation into vaccines targeting an immune response to a range of different diseases. SAVINE antigens are encoded as synthetic genes which, together with a delivery technology such as BioDiem's LAIV-based vaccine vector technology, can be used to develop novel vaccines.

BDM-I is a synthetic compound targeted at the treatment of serious human infections. BDM-I is in the preclinical stage with outlicensing as the intended outcome. BDM-I is active against a range of pathogenic micro-organisms including gram-positive and gram-negative bacteria, fungi and protozoa. Key patents have been filed around BDM-I's antimicrobial activity, including for activity against *Plasmodium falciparum*, responsible for causing the most commonly severe form of malaria, and *Trichomonas vaginalis*, the protozoan responsible for causing a common sexually transmitted disease named trichomoniasis.

BioDiem is also developing BDM-E, a tetra peptide synthetic compound, as a treatment for ophthalmic disorders. The US Food & Drug Administration (USFDA) has granted Orphan Drug designation to BDM-E for the treatment of retinitis pigmentosa, a serious degenerative disease of the retina.

BioDiem's research is ongoing in partnership with internationally recognised laboratories.

For additional information, please visit www.biodiem.com.

Contact

Investors

Julie Phillips, Chief Executive Officer

BioDiem Ltd

Phone +61 3 9613 4100 Email jphillips@biodiem.com Media

Tom Donovan
Buchan Consulting

Phone +61 3 8866 1224 / +61 422 557 107 Email tdonovan@buchanwe.com.au

BDM-E IS RETINOPROTECTIVE IN MODELS OF OXYGEN-INDUCED RETINOPATHY, DIABETIC RETINOPATHY AND LIGHT DAMAGE

GCL

JL Wilkinson-Berka¹, Kirstan Vessey², Michelle Ward², Peter Yee², Erica L. Fletcher².

💹 MONASH University

¹Monash University and ²The University of Melbourne, Melbourne, Australia.

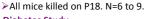
Introduction

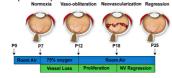
BDM-E is a natural peptide discovered in Russia as an anti-ageing agent. Its precise mode of action is still being determined however a range of effects have been noted for example as a agent that may help prevent or treat eye pathologies. The aim was to determine if BDM-E improves oxygen-induced retinopathy (OIR), diabetic retinopathy and photoreceptor function in a light damage model.

Methods

Oxygen-induced Retinopathy (OIR) Study

- >OIR: C57BL/6 mice in 75% oxygen from postnatal day (P) 7 to P18.
- >Sham Controls: C57BL/6 mice in room air (P7-P18).
- ➤ BDM-E treatment: Early intervention: P7 to P18 Late intervention: P12 to P18
- Doses: 0.5 to 500µg/mouse/day





*P<0.05 to OIR control **P<0.01 to OIR control

Arrows, blood vessels

GCL, ganglion cell layer

% lectin-labelled neovascular tufts per retina 0 7 7 9 9

40 area 20 retina

10

IPL, inner plexiform layer

OIR+250

***P<0.001 to OIR control *P<0.0001 to sham controls

Diabetes Study

Late Intervention

40

- > Diabetes: Sprague Dawley rats administered streptozotocin (55mg/kg).
- Non-diabetic: Sprague Dawley control (0.1M citrate buffer).
- > BDM-E treatment: 20 weeks at 1,10, 50 or 100mg/kg/day. N=5 to 14. **Light Damage Study**
- > Sprague Dawley rats exposed to 250lux/night light and then 10,000 lux for 16 hours. Retina evaluated 30 hours later.
- ▶ BDM-E treatment: 50mg/kg/day from induction of light damage. N=7 to 12.

Results

OIR: BDM-E reduced neovascularization and gliosis

Figure 1: Blood vessel profiles (BVPs) are reduced with BDM-E (250 and 500µg) in both late and early intervention groups.

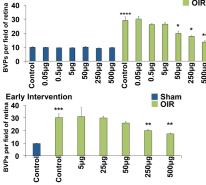


Figure 2: BDM-E reduced neovascularization & avascular retina.

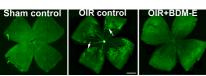
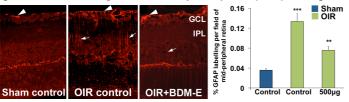


Figure 3: BDM-E reduced glial acidic fibrillary acidic protein (GFAP) labelling.



Diabetes: BDM-E reduced leukostasis and acellular capillaries

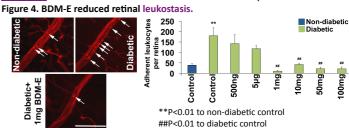
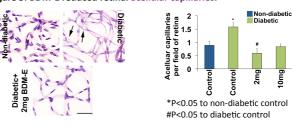


Figure 5: BDM-E reduced retinal acellular capillaries



Light Damage: BDM-E improved retinal function reduced photoreceptor death

Figure 6: BDM-E reduced losses in the electroretinogram.

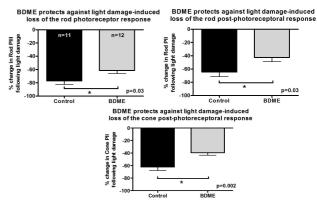
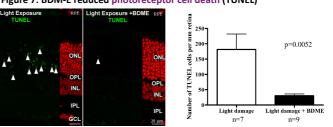


Figure 7: BDM-E reduced photoreceptor cell death (TUNEL)



Conclusions and Acknowledgements

BDM-E effectively reduces vascular injury and neuronal and glial damage in a variety of retinal pathologies. BDM-E may have potential as a retinoprotective

This work was supported by BioDiem Ltd., Melbourne, Australia JW-B is a Senior Research Fellow of the National Health and Medical Research Council (NHMRC) of Australia.