

## ASX Announcement

### BioDiem granted European patent for BDM-I antimicrobial

#### Highlights

- **European Patent Office grants patent protecting BDM-I's use as treatment for common women's health complaint**
- **Patent claims acknowledge BDM-I's broad-spectrum activity against variety of common bacterial and fungal conditions**
- **Additional patent applications filed in Europe around further indications for BDM-I**

**Melbourne, 8 August 2012:** Australian vaccine development company BioDiem Ltd (ASX: BDM) announced today the successful granting of a key European patent for its synthetic antimicrobial compound BDM-I. BDM-I is a novel compound active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa. The patent provides protection around BDM-I as a treatment for vulvovaginitis, a general term for inflammation of the vulva or vagina.

As previously announced, BioDiem has entered into a relationship with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). The USAMRIID is undertaking preclinical studies to screen for BDM-I's activity *in vitro* against a range of disease-causing agents.

BioDiem is using NIAID's<sup>1</sup> In Vitro Assessment for Antimicrobial Activity Service<sup>2</sup> to assess BDM-I's activity *in vitro*. Results are encouraging and BioDiem will discuss with NIAID the potential to use NIAID's Animal Models of Infectious Disease Service<sup>3</sup> to further evaluate BDM-I's activity.

The target markets of antifungals and antibacterials are both extremely large with the market for antifungals estimated to reach US\$11.3 billion in 2014 and the market for anti-infectives generally forecast to exceed \$100 billion by 2015. The continued rise in antibiotic-resistant strains of bacteria such as MRSA (methicillin-resistant *Staphylococcus aureus*) has led to significant interest in such compounds.

BioDiem CEO Julie Phillips said: "We are pleased to secure this key patent for BDM-I. Europe is of course a major regulatory market and this addition to the BDM-I package helps de-risk the asset as a licensing target, increasing its value to BioDiem. The novel antimicrobial space is a highly desirable area for development, and we are pleased to see the accumulation of independent evidence for BDM-I's broad-spectrum antimicrobial activity. We believe this will widen the number of parties potentially interested in licensing BDM-I".

Vulvovaginitis is commonly caused by infection from a range of different micro-organisms. It is one of the most common female health complaints across all demographics. Significantly, the new patent for BDM-I secures a claim around the compound's activity against the organisms *Candida albicans*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* (among others). This group represents some of the most common causative agents for vulvovaginitis, providing more evidence for the breadth of BDM-I's potential applications. *C.albicans* is one of the most common causes of yeast infections and is commonly referred to as thrush, *N.gonorrhoeae* causes gonorrhoea, and *T.vaginalis* is the most common sexually transmitted protozoan infection in industrialised countries. Trichomoniasis has been correlated with reproductive issues and increased susceptibility to a range of other health issues including infection with HIV.

In accordance with BioDiem's development program designed to accelerate opportunities to outlicense BDM-I, a number of new nonclinical studies have been completed to better characterise the compound, which has been manufactured to GLP (Good Laboratory Practice) standards. Preparatory physicochemical studies have provided formulations that can be used for *in vitro* and also *in vivo* assessment in disease models.

In addition the Company has completed a first study in collaboration with the Queensland Institute of Medical Research (QIMR) towards investigation of BDM-I in a proof-of-concept model against schistosomiasis, which is a parasitic disease that causes impairment of growth and cognitive development in patients. Currently 200 million people are infected with schistosomiasis, with 600 million people at risk of infection.

1 NIAID is the National Institute of Allergy and Infectious Diseases, an institute of the US National Institutes of Health (NIH)

2 <http://www.niaid.nih.gov/LabsAndResources/resources/dmid/invitro/Pages/invitro.aspx>

3 <http://www.niaid.nih.gov/labsandresources/resources/dmid/animalmodels/Pages/default.aspx>

It is one of the largest neglected diseases of the developing world. The study's results were encouraging and further studies will be pursued.

Patents for BDM-I have been granted in the US, China, Russia, Singapore, South Africa and Australia whereas National Phase prosecution continues in other major markets. BioDiem has also filed additional divisional patents in Europe and the US for BDM-I.

"BioDiem continues to develop data supporting BDM-I's broad-spectrum antimicrobial activity with the aim of substantially increasing the value of the compound in future licensing agreements", said BioDiem Chief Executive Officer Julie Phillips.

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 anti-microbial 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 BHT 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.

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 partnerships with internationally recognised laboratories.

### **About BDM-I**

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.

BioDiem has benefited from work conducted by major research institutions in the United States that have undertaken R&D studies of BDM-I at reduced cost to BioDiem. Other US patents cover BDM-I's activity against *Plasmodium falciparum*, the protozoan (a type of microorganism) 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.

The new patent supplements the existing US patent grant for BDM-I's activity against the extremely common condition of vulvovaginitis (vaginal inflammation), expanding BDM-I's intellectual property protections across major new indications. Notably the patent granted for BDM-I's activity in vulvovaginitis specifically includes some of the most prevalent vaginitis-causing microorganisms.

For additional information, please visit [www.biodiem.com](http://www.biodiem.com)

### **Contact**

#### **Investors**

Julie Phillips, Chief Executive Officer  
BioDiem Ltd  
Phone +61 3 9613 4100  
Email [jphillips@biodiem.com](mailto:jphillips@biodiem.com)

#### **Media**

Tom Donovan  
Buchan Consulting  
Phone +61 3 8866 1224 / +61 422 557 107  
Email [tdonovan@buchanwe.com.au](mailto:tdonovan@buchanwe.com.au)