BIODIEM LTD
ABN 20 096 845 993
Level 10, South Tower,
459 Collins Street,
Melbourne, Victoria, 3000
Australia
www.biodiem.com

ASX Announcement

Japanese Patent Office to grant BioDiem new patent for BDM-I antimicrobial

Highlights

- **Japan Patent Office to grant 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**
- **Patent will supplement BDM-I's current patent portfolio claims in the United States, Europe and Canada**

Melbourne, 21 November 2012: Australian infectious disease therapy development company BioDiem Ltd (ASX: BDM) announced today the successful application for the grant of a key Japanese patent for the Company's antimicrobial compound, BDM-I. This signals the achievement of patent coverage for BDM-I in the world's three largest patent jurisdictions.

BDM-I is active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa. The new Japanese patent provides protection around BDM-I as a treatment for vulvovaginitis, a general term for inflammation of the vulva or vagina. 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.

Specifically, the patent covers BDM-I as an antimicrobial compound for vulvovaginitis caused by a number of bacterial, fungal and parasitic agents such as *Neisseria gonorrhoea*, *Candida albicans* or *Trichomonas vaginalis*, respectively. *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. Infection with *T.vaginalis* has been correlated with reproductive issues and increased susceptibility to a range of other health issues including infection with HIV.

BioDiem CEO Julie Phillips said: "We are pleased to secure yet another key patent for BDM-I. Japan is a major regulatory market and successful granting of a Japanese patent is a milestone for BDM-I's protection for this major indication across the world's largest patent jurisdictions. Along with our recently initiated research project with Griffith University exploring new variants of BDM-I with enhanced commercial characteristics, this is a good progression of the BDM-I package."

The rise in resistant infections has energised investment in novel antimicrobials. The market for anti-infectives was valued at US$53 billion in 2011 and is forecast to exceed $100 billion by 2015. The antifungals market was valued at US$9.4 billion in 2010 and estimated to reach US$11.3 billion in 2014.

BioDiem has been actively accelerating its development of BDM-I through reputable partnerships such as with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), the National Institutes of Health and the Queensland Institute of Medical Research (QIMR), while retaining full commercial and intellectual property rights for the work conducted.

Currently BioDiem is progressing further validation of BDM-I's antimicrobial activity through *in vivo* proof of concept testing in models of target diseases including fungal, bacterial and parasitic models (schistosomiasis); conducting further studies to explore the scope of BDM-I's indications with expanded screening studies, and embarking on a new project in collaboration with Griffith University.

BioDiem continues to utilise NIAID[1]'s In Vitro Assessment and Antimicrobial Activity Service[2]. Depending on the results and NIAID approval, BioDiem in the future may use NIAID's Animal Models of Infectious Disease Service[3] to further evaluate BDM-I's activity.

Patents for BDM-I have been granted in the US, Europe, 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.

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/Labs And resources/resources/dmid/invitro/Pages/invittro.aspx
3 http://www.niaid.nih.gov/LabsAndResources/resources/dmid/animalmodels/Pages/default.aspx

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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 infectious diseases and related cancers. 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.

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 and commercial groups.

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 granted in major markets 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.

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