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Announcement

New BioDiem Japanese infectious diseases patent for BDM-I

Highlights

- Japan Patent Office to grant additional patent protecting BDM-I's use as treatment for range of infections
- Patent claims include *systemic (bloodstream), respiratory, skin or soft tissue and gastrointestinal infections*
- New patent supplements existing Japanese granted claims for vulvovaginitis and protozoal infections
- Patent adds to BDM-I's current patent portfolio which includes other major markets.

Melbourne, 24 December 2014: Australian infectious disease-focused company BioDiem Ltd announced today the successful application for the grant of an additional key Japanese patent for the Company's antimicrobial compound, BDM-I. This complements the existing granted claim set for BDM-I in the world's largest markets including the US, Europe, and China. BDM-I is active against a range of pathogenic micro-organisms. It is currently being developed as a treatment against 'superbugs' or antibiotic-resistant bacteria and fungi. These organisms are of major concern to international healthcare agencies as the number of available treatments for these infections shrinks.

BioDiem's new Japanese patent provides protection around BDM-I as a treatment for infections of the bloodstream, lungs, skin or soft tissue and gastrointestinal tract. These encompass a wide range of infections including those found in patients who are seriously ill in hospital as well as more minor conditions in the community.

Specifically, the patent covers BDM-I as an antimicrobial compound for these infections caused by various micro-organisms including *methicillin-resistant Staphylococcus aureus* (MRSA), *Enterococcus faecalis*, *Streptococcus pyogenes*, *Haemophilus influenzae*, *Proteus mirabilis* and *vulgaris*, *Mycobacterium tuberculosis*, and *Candida* spp.

BioDiem CEO Julie Phillips said: "We are pleased to secure this additional important patent for our antimicrobial BDM-I for its growing patent portfolio. We already have protection for BDM-I across the world's largest patent jurisdictions. Our plan is to develop BDM-I towards use in serious life-threatening infections and then to expand to wider usage. We are seeking investment to accelerate this important and exciting work".

The worldwide concern about the rise in resistant infections has led to incentives for antimicrobial development including the US Generating Antibiotic Incentives Now (GAIN) legislation. This provides potential for extended market exclusivity, fast track and priority status through the FDA. The market for anti-infectives is forecast to exceed \$100 billion by 2015.

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

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About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company that is focussed on developing and commercialising vaccines and infectious disease therapies. BioDiem's business model is to generate income from partnerships including with other *vaccine* and *infectious disease treatment* companies through existing and new licences to its LAIV vaccine and other technologies. Income comes from licence fees and royalties on sales.

BioDiem's lead technology is the LAIV (Live Attenuated Influenza Virus) vaccine technology used for production of seasonal and pandemic influenza vaccines and is given intranasally. This technology is licensed currently to two commercial partners, in India and China, and is licenced to the World Health Organisation as part of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply. Serum Institute of India's Nasovac-S™ is based on BioDiem's technology and is already marketed in India. For additional information, please visit www.biodiem.com

About BDM-I

BDM-I is a small molecule which has demonstrated activity against a wide range of disease-causing microbes such as bacteria, fungi, and parasites. It is currently being researched as a treatment against 'superbugs' or antibiotic-resistant bacteria and fungi. These organisms are of major concern to international healthcare agencies as the number of available treatments for these infections shrinks. If successful in development, BDM-I could be used to treat a range of infections and be used in many different ways e.g. injection, eyedrop, cream, tablet, etc.

BDM-I has been tested *in vitro* against a range of disease-causing microbes such as the bacteria causing Golden Staph [methicillin-resistant *Staph aureus* (MRSA)] and tuberculosis [*Mycobacterium tuberculosis*], the disease-causing fungi *Aspergillus fumigatus*, *Candida albicans*, *Scedosporium* spp., *Pneumocystis carinii* and *Candida glabrata*, potential agents which could be used in biological warfare agents and other serious human pathogens including *Plasmodium falciparum* which causes malaria. While a range of microbes appears sensitive to BDM-I, its action appears selective i.e. not all strains of a genus have been shown to be sensitive. Some of the most sensitive organisms on minimum inhibitory concentration (MIC) screening have been fungal, including *Pneumocystis* and *Scedosporium* species.

Screening studies to investigate the scope of *in vitro* activity of BDM-I have been conducted by groups such as the U.S. National Institute of Allergy and Infectious Diseases (NIAID), United States Army Medical Research Institute of Infectious Diseases (USAMRIID), University of Sydney, RMIT University and Queensland Institute of Medical Research (QIMR). Based on promising *in vitro* data, BDM-I is poised to progress to *in vivo* studies in various infectious disease preclinical models. Investment is sought to take BDM-I to this next milestone of testing in preclinical models of infection to demonstrate proof-of-concept. For additional information, please visit www.biodiem.com.

Further information

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