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BioDiem gets European patent for BDM-1 antimicrobial

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Singapore: Australian vaccine development company BioDiem has been grated 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 for BDM-I as a treatment for vulvovaginitis, a general term for inflammation of the vulva or vagina.

BioDiem has entered into an agreement with the US 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 In Vitro Assessment for Antimicrobial Activity Service 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 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 $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.

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 Julie Phillips.