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

SERUM INSTITUTE OF INDIA PROGRESSES INTERNATIONAL DEVELOPMENT PLANS FOR BIODIEM VACCINES

12 December 2012, Melbourne, Australia: Australian infectious disease therapy and vaccine development company BioDiem Ltd (ASX: BDM) today announced that its commercial partner the Serum Institute of India (SII) has progressed plans to allow international export of BioDiem's LAIV-based flu vaccines. In 2013 the SII will file documentation with both the World Health Organization (WHO) and the Drugs Controller General of India (DCGI) that, once approved, will permit the export of seasonal flu vaccines produced using BioDiem technology to member developing countries of the United Nations.

BioDiem receives royalties on sales of LAIV vaccines to developing countries by the SII, and retains the option to outlicense LAIV for sales to developed countries. The recent acquisition by the SII of a Netherlands-based vaccine business has signalled the furthering of plans by the SII to access developed markets such as Europe, Australia and the US.

Once export is permitted, target export markets will also need to grant regulatory approval for new vaccine products. This process is expected to be aided by the regulatory work with the WHO and the DCGI, as well as by new clinical data arising from the successful completion of a Phase II efficacy trial for a seasonal LAIV flu vaccine. This trial was carried out by the global non-profit organisation Program for Appropriate Technology in Health using vaccine manufactured by the SII. Conducted in Bangladesh, the trial involved approximately 300 children who were given the vaccine in a randomised, placebo-controlled test. The analysis of the trial results is underway.

The LAIV vaccine used in the trial is Nasovac, produced using BioDiem technology and sold under license by the SII to combat swine flu in India. Nasovac is a nasal spray, rather than an injection, which has the benefit of being able to be taken in a single dose and without the need for specially trained staff. An advantage of the LAIV platform is the ease of treating children with a nasal spray rather than an injection.

"The Serum Institute of India is one of the world's largest vaccine manufacturers with significant international reach. We expect that BioDiem's royalty streams will expand significantly when the SII is able to export LAIV flu vaccine. We look forward to working with the SII to aid their expanded commercialisation and export of the LAIV portfolio," said BioDiem CEO Julie Phillips.

Influenza virus is an infectious disease transmitted through the air which can result in common cold-like symptoms, or more serious side-effects such as acute lung problems and severe pneumonia. Influenza vaccination is integral in developing nations such as Bangladesh, where a child has a 50% chance of contracting pneumonia on a given year, and where nearly a third of children with pneumonia also suffer influenza.

BioDiem's LAIV influenza vaccine can be produced using both egg-based and cell-based manufacturing methods and is then collected, purified and tested for safety and efficacy. BioDiem has licensed partners in India and China. These agreements generated A$1.3m in revenue in the 2012 financial year for BioDiem in milestone payments and royalties, complementing the company's diverse development portfolio in the area of infectious disease therapies and vaccines.

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 infectious diseases and related cancers. 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 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 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.

For additional information, please visit www.biodiem.com

About the Serum Institute of India

The Serum Institute of India is one of the world's largest vaccine manufacturers by volume. The SII launched Nasovac™ in India in 2010 and holds an exclusive license to BioDiem's egg-based LAIV technology for the private market in India and a non-exclusive license for the private markets in Mexico, Argentina, Peru, South Africa, Bangladesh, Bhutan, Nepal, Pakistan and Sri Lanka.

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