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Announcement

Seasonal Influenza vaccine using BioDiem's technology approved for sale in India

- Indian regulator grants marketing approval for influenza vaccine using BioDiem's technology
- BioDiem's partner Serum Institute of India to produce nasal spray seasonal influenza vaccine
- New and ongoing source of royalty revenues for BioDiem

Melbourne, 18 February 2014: Australian infectious disease therapy and vaccine development company BioDiem Ltd today announced a seasonal influenza vaccine using the Company's technology has been approved for sale in India.

The trivalent influenza vaccine, developed by partner Serum Institute of India (SII) using BioDiem's Live Attenuated Influenza Virus (LAIV) vaccine technology, has received marketing approval from the Drugs Controller General of India (DCGI).

BioDiem's CEO Ms Julie Phillips said the approval was an important milestone, and heralded the ability of SII to produce and market a vaccine every year targeting seasonal influenza in the world's second most populous country. Sales of this vaccine will result in a new revenue stream for BioDiem via royalty payments.

"This is also the first approval of the seasonal flu vaccine based on our technology outside Russia and so is an important threshold for us to cross", Ms Phillips said.

"SII is a world-class vaccine producer distributing their products to more than 120 different countries. The research and clinical trials which have formed the basis for this approval confirm the value of the LAIV in protecting against 'flu.

"We congratulate SII on this achievement, which takes SII a step closer to export approval for the vaccine to other developing countries."

BioDiem licensed its LAIV influenza technology to SII in exchange for royalties on sales into the private markets in India, South Africa, Argentina, Peru, Mexico, Bangladesh, Bhutan, Pakistan, Nepal, Sri Lanka and New Zealand. Public market usage in developing countries is royalty-free and falls under an agreement with the World Health Organisation.

In 2010 SII launched and marketed Nasovac™, an LAIV technology-based monovalent influenza vaccine targeting prevention of swine flu. Like Nasovac, SII's new trivalent vaccine targeting seasonal influenza will be administered intranasally i.e. by nasal spray. This offers several advantages including pain-free administration without need for an injection and mimicking the natural route of infections (via the nose).

"We are delighted that the LAIV influenza flu vaccine has now been approved by the DCGI for marketing in India," said Dr Suresh Jadhav, Executive Director of SII.

"Protection of the population by immunisation is an important aim to reduce mortality and morbidity associated with flu infection. Our intranasal vaccine is particularly good for immunizing children because they can be a source of infection for adults and also children can be frightened of needles. Our nasal spray makes immunization of children much easier."

BioDiem has also licensed the LAIV influenza technology to Changchun BCHO Biotechnology Co in China.

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About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company developing vaccines and antimicrobials targeting treatment and prevention of infectious diseases and related cancers. BioDiem's business model is to generate income from partnerships including with other vaccine development companies through existing and new licences to its LAIV vaccine and other technologies while pursuing development of its own vaccines. Income comes from licence fees and royalties on sales.

The lead technology is the LAIV (Live Attenuated Influenza Virus) vaccine used for seasonal and pandemic influenza vaccines and is given intranasally. BDM-L, a liver disease-targeting technology platform is underway at the University of Canberra. BioDiem's antimicrobial, BDM-I, is in preclinical development for the treatment of serious infections. BioDiem's retinal product candidate, BDM-E, being developed for retinitis pigmentosa is available for outlicence. For additional information, please visit www.biodiem.com

About the Serum Institute of India

The Serum Institute (SII) is one of the world's largest vaccine manufacturers by volume. SII launched Nasovac™, an LAIV vaccine directed at swine 'flu, 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. For additional information, please visit www.seruminstitute.com.

Further information

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