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Announcement

Chinese FDA gives approval to start LAIV vaccine clinical trials

Melbourne, 24 September 2015: BioDiem Ltd is pleased to announce that Changchun BCHT Biotechnology Company (BCHT) has received IND approval from the Chinese FDA (CFDA). This approval is an important milestone in the development of BCHT's LAIV influenza vaccine manufactured under licence from BioDiem. The IND approval will permit BCHT to commence clinical trials which are planned to start enrolment of patients in December 2015.

According to CFDA's requirement and BCHT's marketing strategy, a Phase I trial will be initially conducted in adults aged 18 to 49 and, thereafter, the trial will enrol younger people aged between 3 and 17 years. The trial protocol is being finalized together with CFDA experts.

Julie Phillips, CEO, BioDiem Ltd, commented "This is a significant milestone for BioDiem. In general, sales for flu vaccines in China are about 40 million to 50 million doses annually, which corresponds to 3-4% of the population. The vaccination rate is very low compared with developed countries and, thus, the flu vaccine market has a great growth potential. A significant benefit of the LAIV 'flu vaccine is that patients are vaccinated by a nasal spray instead of an injection."

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About BioDiem Ltd

BioDiem is an Australian biopharmaceutical company that is focused 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.

BioDiem's antimicrobial technology, BDM-I, is being developed through its subsidiary, Opal Biosciences Ltd. For additional information, please visit www.biodiem.com.

About Opal Biosciences Ltd

Opal Biosciences is an Australian biotechnology company and an innovative player in infectious disease treatment. The unmet need for new anti-infectives is due to increasing resistance to existing antibiotics, more widespread and common difficult-to-treat infections, and the paucity of upcoming new treatments. This need has spurred the EU and US to introduce significant financial incentives to encourage development of new anti-infectives. Opal is currently seeking funding to support the next stage of development of our products:

- Opal-I, an injectable product, and
- Opal-T, which can be applied to the skin.

For more information, please visit www.opalbiosciences.com.