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Announcement

LAIV Influenza Vaccine Approved in China

Melbourne, 28 February 2020: Australian vaccine development company BioDiem Ltd (“BioDiem” or the “Company”) is pleased to announce the approval of Changchun BCHT Biotechnology Co (BCHT)’s LAIV vaccine in China by the Chinese National Medical Products Administration (NMPA), formerly known as the Chinese FDA.

BCHT’s vaccine, “*Influenza Vaccine, Live, Nasal, Freeze-dried*”, is given as a nose spray rather than an injection. BCHT plans to launch its product “*Influenza Vaccine, Live, Nasal, Freeze-dried*” for the 2020-2021 ‘flu season through use of its strong distributor network covering all provinces and municipalities in mainland China, except Tibet.

China-based BCHT holds an exclusive licence from BioDiem for the influenza technology based on the live attenuated influenza virus (LAIV) vaccine technology. BCHT’s licence covers the private sector market of China for pandemic and seasonal influenza vaccines made using an egg-based production method.

BCHT holds a complementary licence to the LAIV for the public market in China via a sublicense from the World Health Organisation. In addition to annual milestone fees BioDiem will receive royalties from the sale of BCHT’s influenza vaccine product in the China private sector market.

The Influenza Market in China

China’s population is almost 1.4 billion. The overall vaccination coverage in China is estimated to be less than 2% but there is interest in increasing awareness about the value of vaccination especially amongst high risk groups i.e. young children, older adults and pregnant women. Where this is undertaken, vaccination coverage increases.

BioDiem CEO Julie Phillips said “The introduction of a needle-free influenza vaccine into the enormous China market is a great step forward for immunizing the Chinese population against the ‘flu especially children. BCHT has applied significant resources to the development of their vaccine including building a state-of-the art manufacturing facility. We are delighted with this news and the prospects for BCHT’s LAIV vaccine in China”.

BCHT’s President, Dr Wei Kong, said “We believe our needle free flu vaccine will be particularly competitive in China where the vaccination levels are growing as is the appreciation of the benefit of protective benefit of immunization against ‘flu. Our company, BCHT, has met the highest standards of development and manufacture through our dedication to this product and our belief in its potential especially in China.”

BCHT is a biopharmaceutical enterprise engaging in research, development, production and marketing of vaccines, biologics and peptide drugs. It is based in Changchun High Tech Zone. Established in 2004, the company now employs more than 900 employees and has developed in-house expertise in vaccine technology development with particular success in the areas of varicella and rabies vaccines.

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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 technology. Income comes from licence fees and royalties on sales.

BioDiem's LAIV (Live Attenuated Influenza Virus) vaccine technology is 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 licensed 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 marketed in India.

BioDiem's subsidiary, **Opal Biosciences Ltd**, is developing its small molecule BDM-I, as a therapeutic to treat serious human infections including those resistant to antibiotics. BDM-I is in the preclinical stage of development and has obtained development assistance from international agencies.

For additional information, please visit www.biodiem.com and www.opalbiosciences.com.

About Changchun BCHT Biotechnology Co (BCHT)

Changchun BCHT Biotechnology Co., established in 2004 and located in Changchun, is a biopharmaceutical enterprise engaging in research, development, production and marketing of vaccines, biologics and peptide drugs.

BCHT has well-established innovative platform by the most talented researchers and with the state-of-the-art facility. The management team consists of the members with strong international background and extensive experience in China in biopharmaceutical industry. BCHT owns among the most advanced R&D laboratories and pilot plants for vaccines in China. Currently, there are two vaccines, varicella and rabies, in the market and many products, such as HIV vaccine, in its developing pipeline. The manufacturing plant, production process and quality assessment and control are fully with the compliance of GMP requirements and some products aim at receiving WHO prequalification in the near future.

BCHT has established a wide cooperation with international partners for technology promotion and product marketing. The company's products have received the certificate or are in the process of registration for the permit of market access in many countries. BCHT is to strategically explore the international market and business opportunity with the partners.

Further information

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