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October 27, 2015 | News | By BioSpectrum Bureau

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Singapore: Sinovac Dalian, subsidiary of China's Sinovac Biotech, has received China Food and Drug Administration approval to begin human clinical trials on its varicella vaccine candidate.

In preparation to begin human clinical trials, Sinovac Dalian is currently finalizing the trial protocol, confirming the site, training staff and preparing for volunteer screening. The company expects to complete the trial in 2017. Simultaneously, Sinovac Dalian is renovating of an existing building on its Dalian campus, which will serve as the commercial production plant for the

varicella vaccine. The plant will have a designed annual capacity of 5 million doses.

The company's varicella vaccine candidate is a live attenuated vaccine derived from a human cell line. Development of the vaccine began in 2010 and the clinical trial application was officially accepted by the CFDA in January 2013, after the preclinical study was completed. The company expects to be able to commercialize its varicella vaccine by the end of 2019. Ultimately, Sinovac plans to develop a measles-mumps-rubella-varicella (MMRV) combination vaccine. The company has licensed a mumps vaccine for sale in China, has clinical trial approval for its internally-developed rubella vaccine and plans to begin development of a measles vaccine.

Currently, the varicella vaccine is sold exclusively in the private-pay market in China by four domestic producers. In some regions, the varicella vaccine is included in the emergency immunization programs of several provinces for free vaccination due to outbreaks.

Mr Weidong Yin, chairman, president and CEO, Sinovac, commented, "Obtaining the clinical trial approval marks a significant step in the R&D process for our varicella vaccine candidate. Once commercialized, this vaccine will be supplied to the existing market demand and support Sinovac Dalian for its asset utilization, cash flow and profitability in the near future, and position us to capture share with the potential market expansion in the coming years. Meanwhile, there is a meaningful opportunity for an MMRV vaccine in the private-pay market in the future. This represents another milestone as we further develop our vaccine product portfolio to fulfill China's unmet medical needs."

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