## Bharat Biotech ties up with Acambis for JE vaccine

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Hyderabad: City-based Bharat Biotech International Ltd has forged a manufacturing and marketing agreement with Cambridge-based Acambis plc relating to the latter's ChimeriVax-JE investigational vaccine against Japanese Encephalitis (JE).

'Despite the availability of JE vaccines for 60 years, the virus continues to cause death and disease. As a result of the significant unmet public health need and in the absence of a safe, single-dose vaccine, World Health Organisation has identified a need for development of a second-generation and affordable JE vaccine that has an acceptable safety profile and requires fewer doses than currently available vaccines," Bharat Biotech president Dr V Krishna Mohan told reporters here.

He said Acambis is preparing to commence pivotal Phase III trials of a single-dose regimen of its ChimeriVax-JE vaccine candidate by the end of 2005, having completed Phase II clinical testing. Current JE vaccines are administered in multiple doses, he added.

Under the present agreement, Bharat Biotech will be responsible for end stage fill or finish processing of ChimeriVax-JE at its facilities in India. Once the vaccine is approved by the Union government, the company will market and distribute the product to neighbouring countries as well. "The Phase III trials will be finished by February 2006 and we will submit the data to the government is the subsequent two months for approval," he said. The trials will be simultaneously carried in Australia too.

The entire process is likely to be completed by next monsoon. "As monsson progresses, we will supply the vaccine depending on the need. We are planning to initially produce a million doses per month and it can be pushed up to five million doses per month," Dr Mohan said. The pricing of this live, attenuated injectable vaccine would be competitive compared to other unsafe vaccines available in India and other south east Asian nations, he averred.

Speaking over video conference from Cambridge, UK, Acambis director (marketing) Mick Garstag said India was one the major JE endemic regions in the world. Other regions include China, Korea, south east Asia and parts of Australia.

"This year, over 2,000 people in Eastern Uttar Pradesh have fallen prey to the disease. About 24 districts have been affected so far in the region, which will require over 70 million dosages of vaccination," Dr Mohan said. Bharat Biotech expects Rs 15 crore from the vaccine in the first year. The initial agreement is for five years and the company expects 40% revenue coming from the vaccine in the coming years.