

## Clinical trials for Bharat Biotech's Chikungunya vaccine

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Phase 1 human clinical trials of the indigenously developed Chikungunya (CHIKV) vaccine by Bharat Biotech is underway in India to evaluate the vaccine's safety, tolerability and immunogenicity. The placebo controlled study involving 60 healthy volunteers would test escalating doses of the vaccine in prime-boost regimen.

The bone-breaking mosquito borne viral fever that caused the major 2006 epidemic possibly entered India from the Indian Ocean islands, and Bharat Biotech was the first Company to have isolated and characterised the epidemic strain.

Bharat Biotech developed the CHIK vaccine using an isolate of the virus from Indian epidemic. The inactivated virus vaccine developed by the in-house R&D was found to be safe and immunogenic in pre-clinical animal testing. After successful completion of product development and pre-clinical testing, the candidate vaccine was approved by the DCG(I) for Phase 1 clinical trials in 2016.

Dr. Krishna Ella, Chairman & Managing Director of Bharat Biotech stated that Chikungunya is one among the modern day most dreaded virus, and developing an efficient vaccine to prevent it means a lot to people at risk for the infection. The pre-clinical studies were promising and the company hopes that the first-in-human clinical trials successfully meets with the clinical endpoints.

The candidate vaccine under development cross neutralized CHIKV isolates of the Asian genotype isolated in 1963 and isolates from the successive Indian epidemics caused by the East Central South African (ECSA) genotype since 2006. While CHIKV exists as three genotypes, there is only a single serotype of the virus. The candidate vaccine developed by Bharat Biotech effectively cross neutralized both the Asian and ECSA CHIKV genotypes.

Bharat Biotech filed a globally pioneering patent in 2007 for CHIKV drawing priority from 2006, and followed up with a second patent in 2011. Patents have been granted in USA, Europe, China, Indonesia, South Africa and is in National Phase in several other countries.

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