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Bharat Biotech Begins Phase I Clinical Trials of HN-VAC - its Cell Culture H1N1 Vaccine

Hyderabad, India, January 19, 2010: Bharat Biotech today announced that it has commenced Phase I clinical evaluation of **HN-VAC**, its cell culture based H1N1 vaccine candidate. Bharat Biotech received the nod from Drugs Controller General of India (DCGI) to conduct the Phase I clinical trials.

This vaccine under development will boost immunity against the new H1N1 influenza strains, and help protect public health as the pandemic evolves. Bharat Biotech is the first company in India to develop, a cell culture based vaccine candidate for influenza, which can serve as a platform technology for both pandemic and seasonal flu vaccines.

"We welcome the decision by DCGI/Ministry of Health (MOH) and we are very excited at the prospect of commencing Phase I testing of HN-VAC in the clinic. I am extremely pleased with the efforts put in by our R&D and Technical Operations teams, as each step of vaccine development has progressed well according to our plans. For the company, this is yet another important milestone in our endeavor to develop vaccines and provide human healthcare solutions. I would also like to thank the DCGI, MOH, and Indian Council of Medical Research, for their proactive and accelerated approval process for this pandemic flu vaccine. Dr. Krishna Ella, Chairman and Managing Director of Bharat Biotech International said.

"In Preclinical evaluation the vaccine candidate triggered a beneficial immune response. The phase I clinical trial has started in Bangalore with more than 150 subjects under evaluation for safety and immunogenicity and is slated for completion within 6 weeks" Dr. Ella commented.

Vaccines are one of the most effective ways to protect people from contracting illness during influenza epidemics and pandemics. H1N1 pandemic influenza is caused by a new virus and virtually everyone is susceptible. Bharat Biotech has an outlay of INR 70 crores towards product development, manufacturing facilities and R&D facilities for this cell culture based H1N1 vaccine. Bharat Biotech has received the H1N1 vaccine strains from WHO/CDC centers.

Pandemic H1N1 influenza was reported in more than 208 countries and with more than 12,500 deaths. India has reported approximately 26,000 cases with more than 1000 deaths.

Cell culture based flu vaccines represent a new generation vaccine technology that removes the need for traditional egg based vaccines. Egg based vaccines



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are limited by the availability of high quality eggs in millions to manufacture the vaccine and require a cumbersome manufacturing process. Cell culture based vaccines would enable Bharat Biotech to respond quickly to pandemics and rapidly increase the manufacturing capacity as required.

About Bharat Biotech International Limited

Bharat Biotech International Limited, Hyderabad, India, is a multidimensional biotechnology company specializing in product-oriented research, development and manufacturing of vaccines and biotherapeutics. Bharat Biotech was established in the year 1996, is engaged in developing next-generation vaccines and biotherapeutics through innovative and collaborative research. Bharat Biotech is one of the first bio-pharma facilities in India to be audited and approved by Korean Food & Drugs Administration (KFDA). Bharat Biotech is also a WHO prequalified manufacturer of Hepatitis-B vaccines for supply to UNICEF and global procurement agencies. Bharat Biotech is one of the largest manufacturer of anti-rabies vaccines in India. INDIRAB[®] is a market leader in India and several countries globally.

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason.

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