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Press Release

ICMR process to develop vaccine to fight Covid 19 pandemic as per globally accepted norms of fast tracking

Safety and interest of people of India the topmost priority

As the entire world is battling the COVID-19 pandemic, development of an effective vaccine is a promising tool to save lives. Though a large number of vaccines are under various stages of development all across the world, it is also important to promote indigenous vaccine development while at the same time ensuring safety, quality, ethics and adherence to all regulatory requirements.

An inactivated COVID-19 vaccine candidate has been developed by Bharat Biotech International Ltd. in collaboration with ICMR – National Institute of Virology, Pune.

After intense characterization and review of all data from BBIL, ICMR is supporting the clinical development as the vaccine candidate appears to be promising. **Based on in-depth scrutiny of the available data from pre-clinical studies, the Drugs Controller General of India has accorded permission to conduct phase 1 and 2 clinical trial.**

In the larger public health interest, it is important for ICMR to expedite the clinical trials with a promising indigenous vaccine. Faced with the unprecedented nature of the COVID-19 pandemic, and the consequent dislocation of the normal life, all other vaccine candidates across the globe have been similarly fast-tracked. **ICMR's process is exactly in accordance with the globally accepted norms to fast-track the vaccine development for diseases of pandemic potential wherein human and animal trials can continue in parallel.**

Now that preclinical studies have been completed successfully, the phases 1 and 2 human trials are to be initiated. The letter by DG-ICMR to investigators of the clinical trial sites was meant to cut unnecessary red tape, without bypassing any necessary process, and speed up recruitment of participants.

Just as red tape was not allowed to become a hindrance in the fast track approval of new indigenous testing kits or for introducing in the Indian market potential COVID-19 related drugs, the indigenous vaccine development process has also been sought to be insulated from slow file movement. The aim is to complete these phases at the earliest, so that population-based trials for efficacy could be initiated without delay.

ICMR is among the world's most reputed organisations in the field of medical research and regulation and its track record of facilitating India's globally respected and acknowledged vaccine and drug industry speaks for itself. Our trials will be done following the best practices and rigour, and will be reviewed, as required, by a Data Safety Monitoring Board (DSMB). While issues raised in public domain from time-to-time by commentators are

welcome, as they form an important part of feedback loop, the best of India's medical professionals and research scientists should not be second guessed for their professionalism or adherence to the highest scientific rigour.

ICMR is committed to treat the safety and interest of people of India as a topmost priority.

About ICMR

The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR has always attempted to address itself to the growing demands of scientific advances in biomedical research on the one hand, and to the need of finding practical solutions to the health problems of the country, on the other. The ICMR has come a long way from the days when it was known as the IRFA, but the Council is conscious of the fact that it still has miles to go in pursuit of scientific achievements as well as health targets. The Council's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders; mental health research and drug research (including traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. For more information, please visit <https://www.icmr.gov.in/>

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