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Bharat Biotech to develop one drop COVID-19 nasal vaccine

03 April 2020 | News

It's built on a flu vaccine "backbone" that has already been shown to be safe and well-tolerated in humans, in Phase I and Phase II clinical trials

Bharat Biotech has announced that a unique intranasal vaccine for Coronavirus 'CoroFlu' is under development. An international collaboration of virologists at the University of Wisconsin–Madison and the vaccine companies FluGen along with Bharat Biotech has begun the development and testing of a unique vaccine against COVID-19 called CoroFlu.

CoroFlu will build on the backbone of FluGen's flu vaccine candidate known as M2SR. Based on an invention by UW-–Madison virologists and FluGen co-founders Yoshihiro Kawaoka and Gabriele Neumann, M2SR is a self-limiting version of the influenza virus that induces an immune response against the flu. Kawaoka's lab will insert gene sequences from SARS-CoV-2, the novel coronavirus that causes the disease COVID-19, into M2SR so that the new vaccine will also induce immunity against the coronavirus.

Sharing details about 'CoroFlu' far-reaching collaboration Dr.Raches Ella, Head of Business Development, Bharat Biotech said, "Bharat Biotech will manufacture the vaccine, conduct clinical trials, and prepare to produce almost 300 million doses of vaccine for global distribution. Under the collaboration agreement, FluGen will transfer its existing manufacturing processes to Bharat Biotech to enable the company to scale up production and produce the vaccine for clinical trials. Raches added, Bharat Biotech has commercialized 16 vaccines, including a vaccine developed against the H1N1 flu that caused the 2009 pandemic."

Refinement of the CoroFlu vaccine concept and testing in laboratory animal models at UW–Madison is expected to take three to six months. Bharat Biotech in Hyderabad, India will then begin production scale-up for safety and efficacy testing in humans. CoroFlu could be in human clinical trials by the fall of 2020.

Four Phase I and Phase II clinical trials involving hundreds of subjects have shown the M2SR flu vaccine to be safe and well tolerated. This safety profile, M2SR's ability to induce a strong immune response, and the ability of influenza viruses to carry sequences of other viruses make M2SR an attractive option for rapidly developing CoroFlu as a safe and effective SARS-CoV-2 vaccine.

"We are going to modify M2SR by adding part of the coding region for the coronavirus spike protein that the virus uses to

latch onto cells and begin infection," says Gabriele Neumann, a senior virologist in Kawaoka's lab and co-founder of FluGen. "CoroFlu will also express the influenza virus hemagglutinin protein, which is the major influenza virus antigen, so we should get immune responses to both coronavirus and influenza."

M2SR is a unique form of the flu virus. It lacks a gene called M2, which restricts the virus to undergoing only a single round of replication in cells.

"The single replication means the virus can enter the cell, but it can't leave," says FluGen co-founder, president and CEO Paul Radspinner. "So, in essence it tricks the body into thinking it's infected with flu, which triggers a full immune response. But since it can't replicate further, you don't get sick."

CoroFlu, like M2SR, will be delivered intranasally. This route of administration mimics the natural route of infection by coronavirus and influenza and activates several modes of the immune system. Intranasal delivery is more effective at inducing multiple types of immune responses than the intramuscular shots that deliver most flu vaccines.

The Kawaoka group will insert genetic sequences from SARS-CoV-2 into M2SR and then assess CoroFlu's safety and efficacy in animal models at UW–Madison's Influenza Research Institute. The institute has a high-level biosafety facility designated Biosafety Level 3 Agriculture with the ability to safely handle and study pathogens like highly pathogenic influenza viruses and the novel coronavirus.

M2SR was developed by FluGen and includes technology exclusively licensed through the Wisconsin Alumni Research Foundation (WARF), which manages patents for UW–Madison. "To confront a global challenge, this is collaborative discovery at its best," says Erik Iverson, CEO of WARF. "The partners in this endeavor — University of Wisconsin researchers, a biotech startup, and an international vaccine developer — are moving forward with a sense of urgency and integrity incumbent upon us as scientists and world citizens."

"The core mission of Bharat Biotech is to apply innovative technologies in addressing the healthcare concerns of the developing world and to provide them with affordable, high quality vaccines and therapeutics," Raches Ella, expressed. "Ninety percent of our vaccines are sold in lower middle-income countries with affordable pricing being core to our business model. We will fervently work toward the successful development of an efficacious COVID-19 vaccine."

THE BIG DIFFERENTIATOR OF 'COROFLU'

- Mucosal immunity (derived in the lining of the nose and respiratory tract) is very critical for respiratory illness. CoroFlu is based on the influenza vaccine and will provide immunity to the H2N2 strain of seasonal influenza. Bharat Biotech is confident CoroFlu will be the most effective in the prevention of COVID-19.

Today, infectious diseases not only kill people, but hurt the economy of the country, says Dr. Raches Ella. Of Late, we have more seasonal flu problems in the country which is also getting into pandemic as recent evidence indicates in Delhi, Hyderabad, and other cities. We are attempting to solve both the problems together with a new approach for the first time in the world.