CEPI PARTNERS WITH BIOLOGICAL E. LIMITED TO ADVANCE DEVELOPMENT AND MANUFACTURE OF COVID-19 VACCINE CANDIDATE

Hyderabad (India), December 29, 2020: CEPI, the Coalition for Epidemic Preparedness Innovationsand Biological E Limited, India (Bio E), a Hyderabad-based vaccines and pharmaceutical company, today announced a collaboration to advance the development and manufacture of Bio E's COVID-19 subunit vaccine candidate. CEPI will initially contribute up to $5m toward the cost of scaling up the process for manufacturing the vaccine, and will explore providing additional funding to Bio E with the goal of potentially enabling the production of 100 million doses in 2021. The candidate has also received seed funding from the Department of Biotechnology, Government of India.

Bio E initiated a Phase 1/2 clinical trial to evaluate the safety and immunogenicity of the vaccine candidate in India in November 2020, and expects interim data from the trial to be available in Q1 of 2021.

CEPI and Bio E are committed to global equitable access of COVID-19 vaccines and have agreed that vaccine output funded by CEPI's investment will be made available for procurement and allocation, if proven to be safe and effective, through the COVID-19 Vaccine Global Access (COVAX) Facility. The COVAX Facility aims to ensure equitable access to COVID-19 vaccines for all countries, at all levels of development, that wish to participate.

THE BIO E COVID-19 VACCINE CANDIDATE

Bio E's COVID-19 vaccine candidate is based on classical vaccine technology of a protein antigen, SARS-CoV-2 Spike RBD, adsorbed to the adjuvant Alhydrogel (Alum), in combination with another approved adjuvant, CpG 1018. The RBD of S1 subunit binds to the Angiotensin Converting Enzyme-2 (ACE2) receptor on host cell membrane and facilitates virus entry.

RBD protein is expressed in yeast Pichia pastoris, and is similar to technology Bio E is employing for large-scale commercial production of Hep B vaccines. The Baylor College of Medicine construct "RBD N1C1" was selected as the final vaccine antigen candidate on the basis of its manufacturability, due to the yields of protein antigen achieved, ease of process steps and favourable formulation aspects.

The combination of Alum with CpG with N1C1 antigen elicited a highly synergistic, balanced immune response in preclinical models. Four formulations with these components are currently being evaluated in a Phase I/ II clinical study in India to select the final vaccine candidate to be tested in subsequent Phase III trials.

Potential advantages of this vaccine candidate include scalability and thermostability, which could make it suitable for deployment at scale in low-resource settings.

Dr Richard Hatchett, CEO of CEPI said:

“The world has made huge strides in developing vaccines against COVID-19, but there is still much work ahead of us and it is absolutely critical that vaccine R&D continues at pace. To end the acute phase of the pandemic, and control the virus in the longer term, we will need a range of safe and effective vaccines that can be manufactured at scale to meet global demand for billions of doses, and deployed to a wide range of populations and settings so that nobody is left behind.

“Bio E’s vaccine candidate has the potential to be produced at scale, and characteristics which could make it suitable for broad distribution in developing countries. I’m pleased to partner with Bio E to progress the development of this promising vaccine.”

Ms. Mahima Datla, Managing Director, Biological E. Limited said:

“We are very happy to have partnered with CEPI on this endeavour. This collaboration with CEPI validates the technology platform BioE is working on for developing an effective COVID-19 vaccine candidate. The initial investment from CEPI comes on the heels of investments from the Bill & Melinda Gates Foundation and Government of India’s Biotechnology Industry Research Assistance Council (BIRAC) under the National Biopharma Mission of Department of Biotechnology, Government of India, and provides the impetus for accelerated efforts towards a successful and scalable outcome for global access.

“Over the past 10 months, the world has witnessed an unprecedented health emergency and is eagerly awaiting a COVID-19 vaccine. We are working tirelessly to produce a safe and effective vaccine against COVID-19 at an unprecedented pace’’ she further added.

ABOUT CEPI’S COVID-19 VACCINE PROGRAMMES

Built on the principles of speed, scale and equitable access, CEPI is supporting the research and development of a diverse portfolio of vaccine candidates based on a range of vaccine approaches. Including Bio E, CEPI has invested in 11 vaccine candidates, nine of which are still in development, and seven of which are in clinical trials.

CEPI has raised US$1.3bn in support of COVID-19 vaccine research and development, but urgently needs $800m in additional funds to achieve its aim of developing three safe and effective vaccines which can be made globally available through COVAX. These funds are vital for CEPI to progress the most promising vaccine candidates in the portfolio through crucial late-stage clinical trials to prove their safety and efficacy, and ultimately to licensure.

ABOUT CEPI

CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, launched at Davos in 2017, to develop vaccines to stop future epidemics. CEPI has moved with great urgency and in coordination with WHO in response to the emergence of COVID-19. CEPI has initiated 11 partnerships to develop vaccines against the novel coronavirus. The programmes will leverage rapid response platforms already supported by CEPI as well as new partnerships. The aim is to advance COVID-19 vaccine candidates into clinical testing as quickly as possible.

Before the emergence of COVID-19 CEPI's priority diseases included Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever and Chikungunya virus. CEPI also invested in platform technologies that can be used for rapid vaccine and immunoprophylactic development against unknown pathogens (Disease X).

Follow our news page for the latest updates.

ABOUT BIOLOGICAL E. LIMITED

Biological E. Limited (BE), a Hyderabad-based Pharmaceuticals & Biologics Company founded in 1953, is the first private sector biological products company in India and the first pharmaceutical company in Southern India. BE develops, manufactures and supplies vaccines and therapeutics. BE supplies its vaccines to over 130 countries and its therapeutic products are sold in India and the USA. BE currently has 8 WHO-prequalified vaccines in its portfolio.

In recent years, BE has embarked on new initiatives for organisational expansion such as developing generic injectable products for the regulated markets, exploring synthetic biology and metabolic engineering as a means to manufacture APIs sustainably and developing novel vaccines for the global market.

Follow us on Facebook, LinkedIn and Twitter

ABOUT COVAX

COVAX is the vaccines pillar of the ACT-Accelerator. It is co-led by CEPI, Gavi, the Vaccine Alliance, and the World Health Organization (WHO) – working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, Civil Society Organisations and others. COVAX is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to economies of all financial means.

MEDIA CONTACTS

CEPI
Email : press@cepi.net
Phone: +44 7387 055214

Biological E. Limited
K. Vijay Amruth Raj
Email
: Vijay.Kammari@biologicale.com
Phone: +91 83740 77433