CEPI to co-fund Vaxxinity's pivotal Phase 3 UB-612 heterologous booster trial to combat SARS-CoV-2 variants

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OSLO, Norway and DALLAS, April 06, 2022 (GLOBE NEWSWIRE) -- The Coalition for Epidemic Preparedness Innovations (CEPI) and Vaxxinity, Inc. (Nasdaq: VAXX), a US company pioneering the development of a new class of immunotherapeutic vaccines, today announced that they will co-fund the ongoing global pivotal Phase 3 clinical trial of Vaxxinity's next generation UB-612 COVID-19 vaccine candidate as a heterologous – or 'mix-and-match' – booster dose. CEPI will provide up to $9.25m in funding.

The Phase 3 trial, which began in the US earlier this year, is evaluating the ability of UB-612 to boost COVID-19 immunity against the original strain and multiple variants of concern including Omicron - in people aged 16 years or older, who have been previously immunized with an authorized COVID-19 vaccine. Prior to joining the trial, participants will have received a primary regimen of one of the vaccines developed by Oxford-AstraZeneca, Pfizer-BioNTech, Sinopharm, or Sinovac, all of which are being distributed by COVAX, which primarily supplies to low- and middle-income countries (LMICs). Participants are being assessed for safety and immunogenicity after a single booster dose of UB-612, or a homologous booster (i.e., a booster dose of the same vaccine the participant has received before), enabling comparisons between UB-612 and other regimens. Details on the Phase 3 UB-612-305 clinical trial can be found at clinicaltrials.gov using Identifier NCT05293665.

Approximately 1,000 healthy adults will take part in the Vaxxinity-sponsored multi-center international trial, with the first subjects already dosed in the US. The primary immunogenicity analyses will be available in the second half of 2022. If successful, this trial may enable global authorizations, including in high income countries and LMICs.

Data on mix-and-match combinations of vaccines – like those being assessed in this trial - will contribute to the design of flexible vaccination strategies aimed at controlling COVID-19 and combatting emerging SARS-CoV-2 variants. UB-612 can be manufactured at scale and data generated so far support storage conditions that potentially make it especially suitable for use in LMICs. In line with CEPI's Equitable Access Policy, all data from the clinical trial will be shared through open-access publications and via scientific meetings to ensure that all can benefit from the research, and that the data can be used to inform the recommendations of policy makers and regulatory authorities on the use of COVID-19 vaccines.

Dr Richard Hatchett, CEO of CEPI, said:

"As we strive to stay one step ahead of COVID-19, mix-and-match boosters could play an important role in protecting people against new variants by improving the strength and breadth of immune responses. This CEPI-supported trial will generate additional evidence to inform booster strategies in people previously vaccinated with vaccines distributed through COVAX, including against variants of concern."

Mei Mei Hu, Co-Founder and CEO of Vaxxinity, said:

"We greatly appreciate the support from CEPI at this critical time in the pandemic. As we reach majority vaccination levels in high income countries, we must remember that LMICs lag far behind. With our mission to democratize health, we strive to deliver transformational science-led innovation that is not only safe, well-tolerated and accessible to all but is intended to be variant-ready and may protect against new SARS-CoV-2 variants."

Expanding access to COVID-19 vaccines by filling R&D gaps

This is the latest programme to be funded in response to a CEPI Call for Proposals launched in January 2021 which aims to address current gaps in our clinical knowledge of vaccine performance both now and in the long term, in order to expand access to COVID-19 vaccines as part of the global vaccination rollout. Examples of such gaps include assessment of the safety and effectiveness of COVID-19 vaccines in pregnant women, infants and children, and immunocompromised populations, as well as studies on booster doses, length of vaccine efficacy, mix-and-match strategies, and dosing intervals. In response to this Call for Proposals, CEPI is also funding a study of COVID-19 vaccines in immunosuppressed and transplant patients, a project to expand access to BBIBP-CorV in Africa, a clinical trial of mix-and-match combinations of vaccines in Pakistan, and a mix-and-match booster study in Taipei. In addition, CEPI has previously announced funding to support a mix-and-match study led by the University of Oxford, and is supporting trials to evaluate fractional COVID-19 booster shots in multiple countries.

This work forms part of CEPI's next 5-year plan, published in March 2021, which aims to reduce or even eliminate the future risk of pandemics and epidemics. As part of this plan CEPI is working to strengthen our defences against COVID-19 and reduce the risk of future coronavirus pandemics, by optimizing our current vaccines, addressing variants of concern, developing next-generation COVID-19 vaccines, and initiating the development of broadly protective or universal coronavirus vaccines.

About CEPI
CEPI is an innovative partnership between public, private, philanthropic, and civil organizations, launched at Davos in 2017, to develop vaccines against future epidemics. Prior to COVID-19 CEPI's work focused on developing vaccines against Ebola virus, Lassa virus, Middle East Respiratory Syndrome coronavirus, Nipah virus, Rift Valley Fever virus and Chikungunya virus – it has over 20 vaccine candidates against these pathogens in development. CEPI has also invested in new platform technologies for rapid vaccine development against unknown pathogens (Disease X).

During the current pandemic, CEPI initiated multiple programmes to develop vaccines against SARS-CoV-2 and its variants with a focus on speed, scale and access. These programmes leverage the rapid response platforms developed by CEPI's partners prior to the emergence of COVID-19 as well as new collaborations. The aim is to advance clinical development of a diverse portfolio of safe and effective COVID-19 vaccine candidates and to enable fair allocation to these vaccines worldwide through COVAX.

CEPI's 5-year plan lays out a $3.5 billion roadmap to compress vaccine development timelines to 100 days, develop a universal vaccine against

COVID-19 and other *Betacoronaviruses*, and create a “library” of vaccine candidates for use against known and unknown pathogens. The plan is available at: https://endpandemics.cepi.net/.

Follow our news page for the latest updates. Follow us via @CEPIvaccines, @DrRHatchett, and LinkedIn.

About UB-612
UB-612 is the first multitope subunit protein/peptide-based vaccine candidate for SARS-CoV-2, which is designed to activate both B and T-cell arms of the immune system. Phase 1 and Phase 2 trials of UB-612 conducted in ~4000 participants have shown UB-612 to be well tolerated with no vaccine-related serious adverse events. The most striking findings were induction of long-lasting virus neutralizing antibodies, broad T-cell immunity against SARS-CoV-2 variants and a strong booster memory recall inducing high levels of neutralizing antibodies against Delta, Omicron and other variants. UB-612 is now in a pivotal Phase 3 trial.

About Vaxxinity
Vaxxinity, Inc. is a purpose-driven biotechnology company committed to democratizing healthcare across the globe. The company is pioneering a new class of synthetic, peptide-based immunotherapeutic vaccines aimed at disrupting the existing treatment paradigm for chronic disease, increasingly dominated by monoclonal antibodies, which suffer from prohibitive costs and cumbersome administration. The company’s proprietary technology platform has enabled the innovation of novel pipeline candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer’s, Parkinson’s, migraine, and hypercholesterolemia. The technology is also implemented as part of a COVID-19 vaccine program. Vaxxinity has optimized its pipeline to achieve a potentially historic, global impact on human health.

Forward-looking Statement
This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "believe," "may," “continue,” “advancing,” “aim,” “strive,” “intend,” "will" and similar expressions, are intended to identify forward-looking statements. These forward-looking statements involve substantial risks and uncertainties, including statements that are based on the current expectations and assumptions of Vaxxinity’s management about the development of a new class of immunotherapeutic vaccines, the potential outcome and findings of Phase 3 trials for UB-612 and the innovation and efficacy of Vaxxinity’s product candidates. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements. Additional important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022. The forward-looking statements are made as of this date and Vaxxinity does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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