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Sabin Vaccine Institute Receives up to $6.3 Million from CEPI for Dose-Optimizing COVID-19 Vaccine Clinical Trial

WASHINGTON, D.C. – May 17, 2022 – The Sabin Vaccine Institute was awarded up to $6.3 million from the Coalition for Epidemic Preparedness Innovations (CEPI) for a clinical trial to evaluate the immunogenicity and safety of lower, fractional doses of registered COVID-19 vaccines used as a booster dose. This dose optimizing trial will allow us to understand if smaller doses of COVID-19 vaccines generate similar immune responses to full doses. It will also provide key information as to whether lower doses may have fewer side effects, potentially increasing vaccine acceptance.

“This research has the potential to have the biggest impact in the places that need it the most,” said Amy Finan, CEO of the Sabin Vaccine Institute. “Just 1 in 6 people, 17.4%, have received a COVID-19 vaccine in low-income countries, compared to 72% in high income countries. There are currently sufficient global supplies of vaccine to meet demand, but that situation could change once again. The only way to end this pandemic is to ensure that everyone, everywhere has access to vaccines. That was Dr. Sabin’s goal during his lifetime, and it’s the goal now of the Sabin Vaccine Institute and this research.”

This Phase 4 dose-optimizing trial will be conducted in Brazil and Pakistan, with 1,440 participants per country. Participants will receive either a full or a fractioned booster dose of Pfizer/BioNTech (full, half and one-third doses), AstraZeneca (full and half doses), and Sinovac (only full doses) COVID-19 vaccines, given a minimum of six months following the primary two-dose schedule or following natural infection. Researchers will follow participants over a minimum of six-months after the booster dose during which time, the immune response from study groups receiving full and fractioned booster doses will be assessed and compared. The study will also describe the safety and reactogenicity profile of fractional and full booster doses.

Data from this trial may support vaccination recommendations and strategies. While global COVID-19 vaccine supply has ramped up in recent months and there is not currently a vaccine shortage, both vaccine supply and demand will remain variable over time. Should fractional COVID-19 vaccine booster dosing strategies prove successful, this approach could provide a prudent way to maximise the availability of future COVID-19 vaccine doses if needed – for example if demand was to increase following the emergence of a new variant – thereby contributing to equitable access.

“We are very excited about this important study. Optimizing vaccine dosing has the potential to further increase supply, and subsequently increase vaccine equity,” said Dr. Denise Garrett, Sabin vice president of Applied Epidemiology. “The COVID-19 pandemic created pressure for an effective vaccine, which lead to large doses being tested to ensure efficacy; however, if we find that lower doses can be as effective as full doses, more vaccines may be available for more people if they are needed.”

This strategy was successful in addressing previous vaccine shortages. The WHO Strategic Advisory Group of Experts on Immunization has previously recommended lower doses of yellow fever and polio vaccines to vaccinate more people during outbreaks. In both cases research showed that fractional dosing offered similar protection while extending supply. If successful, this COVID-19 fractional dose

research could help policymakers make more informed decisions about allocating vaccines, and free doses for both primary and booster vaccination.

This clinical trial is funded by CEPI, an innovative global partnership working to accelerate the development of vaccines against epidemic and pandemic threats so they can be accessible to all people in need. Grant management support will be provided by PATH, an international nonprofit global health organization. This is the third award to be made as part of CEPI's fractional COVID-19 dose program, launched to fund clinical trials looking at the impact of dose-sparing COVID-19 booster shots. It forms part of the coalition's work to expand research on the performance of existing COVID-19 vaccines so that currently available tools can be best used for maximum public health impact.

CEPI's Director of Clinical Development, Vaccine R&D, Jakob Cramer, said: "As shown during past rollouts of reduced polio and yellow fever vaccine shots, offering fractional COVID-19 vaccine booster doses could provide several benefits to global COVID-19 vaccination campaigns, including maximising the availability of booster doses if needed and exploring whether reduced booster doses minimize the number of side effects following administration. Our new partnership with Sabin Vaccine Institute and PATH will provide critical insights into this fractional dose approach. The results from the trial to be conducted in Brazil and Pakistan will help guide our ongoing response to this devastating pandemic."

In line with CEPI's open access policy, data and results from the clinical trial will be shared through searchable, peer-reviewed scientific literature and in scientific meetings to ensure all can benefit from the research.

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About the Sabin Vaccine Institute

The Sabin Vaccine Institute is a leading advocate for expanding vaccine access and uptake globally, advancing vaccine research and development, and amplifying vaccine knowledge and innovation. Unlocking the potential of vaccines through partnership, Sabin has built a robust ecosystem of funders, innovators, implementers, practitioners, policy makers and public stakeholders to advance its vision of a future free from preventable diseases. As a non-profit with more than two decades of experience, Sabin is committed to finding solutions that last and extending the full benefits of vaccines to all people, regardless of who they are or where they live. At Sabin, we believe in the power of vaccines to change the world. For more information, visit www.sabin.org and follow us on Twitter, @SabinVaccine.

About CEPI
CEPI is an innovative partnership between public, private, philanthropic, and civil organisations, 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 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 **http://www.endpandemics.cepi.net**.

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