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Press release

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Siemens Healthineers and Nanogen collaborate on clinical trials of Nanogen's vaccine candidate 'Nanocovax'

- **First such clinical trial collaboration for Siemens Healthineers in Asia Pacific in the development of COVID-19 vaccine candidates.**
- **Antibody tests play a significant role in measuring the protective immune response elicited by vaccines; Siemens Healthineers SARS-CoV-2 IgG antibody test is being used to assess this immune response.**
- **Phase 2 study showed robust immune responses; Phase 3 study has commenced with 13,000 subjects.**

Siemens Healthineers announces its collaboration with Nanogen Pharmaceutical Biotechnology to utilize Siemens Healthineers SARS-CoV-2 IgG antibody test (sCOVG) in Nanogen's Nanocovax vaccine clinical trials for COVID-19. This is a first-of-its-kind collaboration for Siemens Healthineers in Asia Pacific, which will facilitate the quantitative measurement of SARS-CoV-2 IgG antibodies in vaccinated subjects and help assess the level of potentially protective immune responses induced by the Nanocovax vaccine.

Nanocovax, researched and developed by Nanogen, consists of recombinant spike-protein subunits bound to silica nanoparticles. A Phase 2 study of Nanocovax was successfully conducted with 560 subjects and robust immune responses, including a strong IgG response as measured by the sCOVG test were observed in all vaccinated subjects. Phase 3 study has commenced with the recruitment of 13,000 subjects.

As part of the evaluation of study subjects, Nanogen required an antibody test against the spike protein that could deliver quantitative results, had good correlation to virus neutralization titer and could be deployed in a high throughput manner. Correlation between sCOVG to a virus neutralization test was previously performed and the result showed a strong relationship between the test and virus neutralizing titer. Siemens Healthineers sCOVG met Nanogen's criteria and was subsequently selected for use. Study subjects have their anti-spike IgG antibody levels measured using this test at baseline and at multiple time points, post-vaccination. This data will allow Nanogen to assess the level of immune response elicited by Nanocovax.

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Interim analysis of Phase 2 study results showed that Nanocovax elicited anti-spike IgG responses in all vaccinated subjects and these responses were well detected by the sCOVG. IgG antibodies indicate the development of a mature adaptive immune response and may be more effective than other antibody isotypes in triggering additional anti-viral pathways beyond virus neutralization[1]. In addition, IgG antibodies may persist longer than other antibody isotypes. Therefore, IgG-specific tests are commonly used to evaluate the immune response after vaccination or infection.[2]

"Siemens Healthineers values this collaboration with Nanogen", said Philipp Breschan, General Manager, Siemens Healthineers, Vietnam. "We are pleased that the Siemens Healthineers SARS-CoV-2 IgG test met Nanogen's stringent selection criteria. We will continue to support Nanogen in this crucial project in the fight against the pandemic."

"Our decision to develop Nanovax was to extend our support to the Vietnam government's COVID-19 fight. Nanogen appreciates Siemens Healthineers support in our clinical trials of Nanovax. The SARS-CoV-2 IgG assay on an automated platform meets the reference labs' requirement, as well as provides the data to assess the level of immune responses elicited by our vaccine", said Dr. Do Minh Si, Director of Research and Development, Nanogen Pharmaceutical Biotechnology.

Disclaimer

1. For discussion of additional anti-viral functions including complement fixation, NK cell activation and opsonization, please refer to Chapter 9-12 of Immunobiology, 5th edition, Janeway et al (2001). https://www.ncbi.nlm.nih.gov/books/NBK27162/
2. US CDC https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

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About Siemens Healthineers

Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostics, image-guided therapy, in-vivo diagnostics, and innovative cancer care. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2020, which ended on September 30, 2020, Siemens Healthineers generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Following the acquisition of Varian Medical Systems, Inc. the company has approximately 65,000 employees worldwide. Further information is available at www.siemens-healthineers.com/en-vn

About Nanogen Pharmaceutical Biotechnology

Established in 1997 and headquartered in Ho chi Minh City, Vietnam, Nanogen Pharmaceutical Biotechnology is a leading company that develops, manufactures and markets novel active Biopharmaceutical ingredients (APIs) based on advances in recombinant DNA and protein technologies. Nanogen offers a variety of gene-to-therapy biopharmaceuticals for the treatment of hepatitis B, hepatitis C, anemia due to chronic renal failure, oncology, etc. Its therapeutic injection products are developed, manufactured and marketed under strict compliance with current GMP and tight QC/QA procedures, and are sold in various countries in Asia, Europe, Africa and America.