



## **Atrium Health Opens Preventive Vaccine Clinical Trial for COVID-19**

Enrollment of volunteers for a phase 3 study of Novavax' vaccine candidate against COVID-19 to begin immediately

CHARLOTTE, N.C., January 7 – Atrium Health announced today it will participate in a phase 3 COVID-19 investigational vaccine clinical trial in the fight against coronavirus disease 2019 (COVID-19). The clinical trial will test the safety, immunogenicity and effectiveness of NVX-CoV2373, developed by U.S. company Novavax, Inc., a late-stage biotechnology company developing next-generation vaccines for serious infectious diseases.

Atrium Health's vaccine research program, "STRIVE for Healthier Futures," will have oversight of the enrollment and management of this clinical trial. STRIVE, which stands for strategic research, innovation, vaccines and engagement, is comprised of a diverse, multi-disciplinary team of researchers, scientists, physicians and other medical experts within the Atrium Health enterprise. STRIVE was developed with a goal of identifying one or more vaccines that prevent COVID-19 and will reduce its spread among the population.

"Atrium Health is the only site in the region offering the Novavax clinical trial," said Dr. Christine Turley, vice chair of research at Atrium Health Levine Children's and lead physician investigator of STRIVE. "We've been extremely thorough and diligent in reviewing many clinical trials, and are pleased to participate in a phase 3 clinical trial of a promising COVID-19 vaccine candidate. We also know that, with almost 8 billion people on the planet, there will need be more than one FDA-approved vaccine for COVID-19, so we are prepared to launch multiple, additional trials in the near future."

People who join Atrium Health's vaccine registry may be invited to participate in the NVX-CoV2373 trial, as well as additional COVID-19 vaccine trials that Atrium Health may open. To date, the registry has an estimated 4,000 people enrolled; of which, 250 may be invited to participate in the Novavax trial.

Novavax' clinical trial design is harmonized with those of other leading companies and calls for the enrollment of up to 30,000 participants in the United States and Mexico. This clinical trial expects to include proportional representation among diverse populations most vulnerable to COVID-19 distributed across race/ethnicity, age and those living with other serious illnesses that make them more susceptible to the coronavirus, such as cancer or diabetes.

## Enrollment goals are:

- o At least 25% age 65 or older
- At least 25% with high-risk comorbidities
- Defined minority representation, including:
  - At least 15% Black/African Americans
  - Between 10-20% LatinX, and
  - At least 1-2% Native Americans

Turley anticipates a strong, favorable response from the Charlotte community in this trial.

"There are many people who are worried for their own health, and this trial may give them an early benefit," Turley said. "They may have a family member who is considered high-risk, or who cannot participate in a trial. Some people are just altruistic – they believe that vaccines are important, that working together to turn the page on the pandemic through a vaccine is important, and they want to contribute to a cure."

Trial participants will randomly receive either the investigational vaccine or placebo in two doses, 21 days apart. Two-thirds of volunteers will receive the vaccine candidate and one-third will receive a saline-based placebo. Clinical trial participants will be financially compensated for their time spent participating in the trial. The trial will be operated out of two Atrium Health locations in the Charlotte area, along with an innovative mobile program.

A novel approach to making research accessible to the community will be provided through work with Matrix Medical Network, in the form of a mobile clinic fully integrated into the Atrium Health team. The mobile site is outfitted to carry out the clinical trial specifications, including logistics ranging from patient screenings and translation services to safe vaccine storage. This approach allows Atrium Health to meet the volunteers where they are, make the research visible and better ensure that all members of the community, including those with barriers to healthcare access, are included.

Atrium Health is part of the <u>COVID-19 Prevention Network (CoVPN)</u>, which aims to enroll thousands of volunteers in large-scale clinical trials, testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19. The CoVPN is supported by the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

For more information about the NVX-Co specific trial and/or Atrium Health's COVID-19 research registry, call 833-451-1188, visit <u>AtriumHealth.org/COVIDVACCINE</u> or email STRIVEVaccineRegistry @atriumhealth.org.

Atrium Health is a nationally recognized leader in shaping health outcomes through innovative research, education and compassionate patient care. Atrium Health is an integrated, nonprofit health system with more than 70,000 teammates serving patients at 42 hospitals and more than 1,500 care locations. It provides care under the Wake Forest Baptist Health name in the Winston-Salem, North Carolina, region and Navicent Health in Georgia. Atrium Health is renowned for its top-ranked pediatric, cancer and heart care, as well as organ transplants, burn treatments and specialized musculoskeletal programs. A recognized leader in experiential medical education and groundbreaking research, Wake Forest School of Medicine is the academic core of the enterprise, including Wake Forest Innovations, which is advancing new medical technologies and biomedical discoveries. Atrium Health is also a leading-edge innovator in virtual care and mobile medicine, providing care close to home and in the home. Ranked among U.S. News & World Report's Best Hospitals for cancer treatment and in eight pediatric specialties, Atrium Health has also received the American Hospital Association's Quest

for Quality Prize and was the recipient of the 2020 Centers for Medicare & Medicaid Services Health Equity Award for its efforts to reduce racial and ethnic disparities in care. With a commitment to every community it serves, Atrium Health seeks to improve health, elevate hope and advance healing – for all, providing more than \$2 billion per year in free and uncompensated care and other community benefits.

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