<u>10,000 UK volunteers to take part in</u> <u>new COVID-19 vaccine trials</u>

- More than 250,000 people in the UK have now volunteered to take part in COVID-19 vaccine trials through the NHS Vaccines Registry
- tens of thousands of those volunteers will take part in the world's first Phase 3 study to test the effectiveness of the new Novavax coronavirus vaccine
- more volunteers from black, Asian and minority ethnic backgrounds, as well as those with long-term health conditions, are being encouraged to be part of vaccine research

Ten thousand UK volunteers will from today (Friday 25 September) be invited to join a leading phase 3 coronavirus vaccine trial, as the number of people who have signed up to take part in research hits 250,000.

The Phase 3 study will test the safety and effectiveness of a promising new vaccine, developed by US biotechnology company <u>Novavax</u>, across a broad spectrum of people, including those from a variety age groups and backgrounds. Phase 3 studies involve many thousands of people, giving researchers insights into the effects of a vaccine on a much larger population than phase 1 and 2 studies.

Calling on some of the thousands of volunteers who have joined the fight against coronavirus through the <u>NHS Vaccine Registry</u>, the phase 3 trials, which started yesterday (24 September), are the second to commence in the UK and will be undertaken at a number of <u>National Institute for Health Research</u> <u>(NIHR)</u> regional sites across the UK, including Lancashire, the Midlands, Greater Manchester, London, Glasgow and Belfast.

The Registry was launched in July to help create a database of people who consent to be contacted by the NHS to take part in clinical studies, to help speed up the development of a safe and effective vaccine.

With several more trials for potential vaccine candidates expected to start before the end of the year, UK researchers are calling for additional volunteers to sign up to take part in clinical studies. To better understand the effectiveness of vaccine candidates and help find a vaccine that works for as many people as soon as possible, researchers are particularly seeking more volunteers from black, Asian and minority ethnic backgrounds as well as those with underlying health conditions and the over 65s.

Business Secretary Alok Sharma said:

I am incredibly proud of the 250,000 volunteers who have signed up to play their part in the global fight against coronavirus.

Our scientists and researchers are working day and night to find a

vaccine that meets the UK's rigorous safety standards, but we need even more people from all backgrounds and ages to sign-up for studies to speed up this life-saving research.

The more people that sign up, the quicker we can find a safe and effective vaccine, defeat this virus and protect millions of lives.

The UK government has secured 60 million doses of the Novavax vaccine, which will be manufactured using FUJIFILM Diosynth Biotechnologies' facilities in Stockton-on-Tees, north east England. This will ensure that, once approved by regulators, the vaccine can be supplied as quickly as possible.

Professor Paul Heath, Novavax Phase 3 trial Chief Investigator and Professor of Paediatric Infectious Diseases at St George's University Hospitals NHS Foundation Trust said:

This is only the second Phase 3 vaccine trial to be initiated in the UK, and the first Phase 3 trial with the Novavax vaccine anywhere in the world, which shows the importance that has been placed on rapidly finding a solution for this urgent public health need. The vaccine has successfully gone through its early safety trials and we're extremely encouraged by its performance so far.

The NHS Vaccines Registry has been key in helping us quickly identify participants who fulfil the inclusion criteria for this study – particularly those from among groups most likely to benefit from a vaccine, such as the elderly.

Chair of the government's Vaccines Taskforce Kate Bingham said:

Finding a safe and effective vaccine that works for the majority of the UK population is the best way to tackle this devastating disease. Whilst social distancing, testing and other measures can help reduce the impact of coronavirus, the only long-term solution to beating it will be finding a vaccine. One of the ways people can help with that is by signing up to the NHS Vaccines Registry, so they can be rapidly called.

Gregory M. Glenn, M.D., President of Research & Development at Novavax said:

Today marks an important and exciting advance in addressing the global COVID-19 pandemic in Europe and around the world. We are confident in the safety of this vaccine and based on the successful phase 3 clinical trial of our influenza vaccine built using the same platform, we are optimistic that NVX-CoV2373 will prove to be effective at preventing infection and reducing the transmission of the disease.

If any of the vaccines are successful in clinical trials, they could start to be delivered to the UK in 2021. It is expected that these vaccines would first be given to priority groups such as frontline health and social care workers, ethnic minorities, adults with underlying health conditions, and the elderly based on Joint Committee on Vaccination and Immunisation (JCVI) advice.

The UK public can support the national effort to speed up vaccine research and receive more information about volunteering for clinical studies by visiting <u>www.nhs.uk/researchcontact</u>.

Notes to editors

The Novovax vaccine comprises a recombinant nanoparticle technology containing an engineered coronavirus spike protein and the saponin-based adjuvant Matrix-M designed to enhance the immune response and stimulate high levels of neutralising antibodies. Half the study participants will receive the trial coronavirus vaccine, delivered in 2 doses, and half will receive a saline placebo, also delivered in 2 doses – a so called 'blinded trial' in which none of the participants are aware if they are receiving the vaccine or a placebo. Study participants can expect to make around 6 visits to their local trial centre over 13 months.

The UK has secured access to a total of 6 different candidates, across 4 different vaccine types, reflecting the government's strategy to ensure the UK has a supply of vaccines should any of these prove safe and effective through clinical trial research. This is in addition to the University of Oxford's vaccine being developed with AstraZeneca, and includes agreements with the BioNTech/Pfizer alliance, Valneva and GSK/Sanofi Pasteur.

The 4 different vaccine classes that the government has secured to date for the UK are:

- adenoviral vaccines (Oxford/AstraZeneca, Janssen)
- mRNA vaccines (BioNTech/Pfizer, Imperial)
- inactivated whole virus vaccines (Valneva)
- protein adjuvant vaccines (GSK/Sanofi, Novavax)

In addition the UK has secured rights to AstraZeneca's antibody treatment to neutralise the virus which can be used both as a short term prophylactic for those people who cannot receive vaccines (such as cancer and immunosuppressed patients) and front line workers exposed to the virus, as well as a treatment for infected patients in hospitals.

The UK is actively working with the vaccine alliance GAVI, The Coalition for Epidemic Preparedness Innovations (CEPI), the World Health Organisation and a group of other countries to help buy vaccines as well as to ensure equitable distribution of vaccines to low-income countries.

Volunteering for COVID-19 vaccine clinical trials

A new NHS service was launched in July 2020 to enable people across the UK to sign up for information on COVID-19 vaccine trials.

The NHS COVID-19 vaccine research registry, developed in partnership with NHS Digital, will help facilitate the rapid recruitment of large numbers of people into trials over the coming months — potentially meaning an effective vaccine for coronavirus can be found as soon as possible.

The service was commissioned as part of the UK government's Vaccine Taskforce in conjunction with the National Institute for Health Research (NIHR) and the Northern Ireland, Scottish and Welsh Governments

Anyone living in the UK can sign up online to take part in the trials through the NHS, giving permission for researchers to contact you if they think you're a good fit. Once you sign up, you can withdraw at any time and request that your details be removed from the COVID-19 vaccine research registry. The process takes about 5 minutes to complete.

More information can be found: www.nhs.uk/researchcontact

About the Vaccine Taskforce

The Vaccine Taskforce (VTF) was set up under the Department for Business, Energy and Industrial Strategy (BEIS) in May 2020, to ensure that the UK population has access to clinically effective and safe vaccines as soon as possible, while working with partners to support international access to successful vaccines. This is to place the UK at the forefront of global vaccine research, development, manufacture and distribution.

The Vaccine Taskforce comprises a dedicated team of private sector industry professionals and officials from across government who are working at speed to build a portfolio of promising vaccine candidates that can end the global pandemic. It is chaired by biotech and life sciences expert Kate Bingham, who was appointed by the Prime Minister Boris Johnson.

The Vaccine Taskforce's approach to securing access to vaccines is through:

- procuring the rights to a diverse range of promising vaccine candidates to spread risk and optimise chances for success;
- providing funding for clinical studies, diagnostic monitoring and regulatory support to rapidly evaluate vaccines for safety and efficacy; and
- providing funding and support for manufacturing scale-up and fill and finish at risk so that the UK has vaccines produced at scale and ready for administration should any of these prove successful.