UK government secures new COVID-19 vaccines and backs global clinical trial

- Government secures early access to 90 million doses of 2 promising vaccine candidates
- UK to support and provide infrastructure to Novavax in running a Phase 3 clinical trial in the UK, and plans to manufacture their vaccine in the UK with FUJIFILM Diosynth Biotechnologies
- UK will also co-fund a global clinical trial with the Janssen Pharmaceutical Companies of Johnson and Johnson to establish how effective their vaccine could be in providing long-term immunity against COVID-19
- UK has now secured access to 6 different vaccine candidates as part of the government's strategy to build a portfolio of promising new vaccines should any be found to be safe and effective

New in-principle agreements have secured 60 million doses of the Novavax vaccine and 30 million doses of the Janssen vaccine.

Ministers have also agreed in principle to co-fund a ground-breaking global clinical study of the Janssen vaccine. The next phase of clinical trials is expected to begin later this year to look at whether providing 2 doses of their vaccine candidate to participants provides long-term protection against coronavirus.

The UK welcomes Janssen's vaccine being made available on a not-for-profit basis during the emergency pandemic to both the UK and the rest of the world to ensure the global supply and equitable access of a vaccine.

Supported by the government, Novavax will conduct a Phase 3 clinical trial of the vaccine working with National Institute for Health Research (NIHR) to access their clinical network and expertise.

Novavax also plans to manufacture some of the vaccine using FUJIFILM Diosynth Biotechnologies's facilities in Billingham, Stockton-on-Tees. This will ensure that, once available, the vaccine can be supplied to the British public as soon as possible.

If the vaccines are safe and successful in clinical trials, both could be delivered to the UK in mid-2021. They would be given first to priority groups such as frontline health and social care workers, ethnic minorities, adults with serious diseases, and the elderly.

Business Secretary Alok Sharma said:

The government's strategy to build a portfolio of promising vaccine

candidates will ensure we have the best chance possible of finding one that works.

Today's agreements will not only benefit people in the UK but will ensure fair and equitable access of a vaccine around the world, potentially protecting hundreds of millions of lives.

While we are doing everything we can to ensure the British people get access to a successful vaccine as soon as possible, nobody is safe until we are all safe so global cooperation is absolutely critical if we are to defeat this virus once and for all.

With today's announcement, the UK has now secured access to 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. These include the University of Oxford's vaccine being developed with AstraZeneca, as well as agreements with the BioNTech/Pfizer alliance, Valneva and GSK/Sanofi Pasteur.

In addition, a deal with AstraZeneca will provide the UK with access to treatments containing COVID-19 neutralising antibodies to protect those who cannot receive vaccines, such as cancer and immunocompromised patients.

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.

Kate Bingham, Chair of the Government's Vaccines Taskforce, said:

The sooner we start the two-dose study of the Janssen vaccine the sooner we will know whether the vaccine can provide durable, long term protection against COVID-19 infection. The vaccine is based on technology used in its recently approved preventative Ebola vaccine designed to induce long-term immunity in individuals over one years' old.

We are delighted to partner with Janssen that has demonstrated their long-term commitment to global health and vaccines by providing their COVID-19 vaccine across the world at no profit.

It is also encouraging that Novavax's recent clinical data shows their vaccine triggers an immune response greater than that in patients who have recovered from the disease.

Paul Stoffels, M.D. Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson said:

We are delighted to work with the UK government on the global Phase

3 clinical programme for our COVID-19 vaccine candidate, and to ensure it is made available to citizens around the world, if proven to be effective with a good safety profile. Ending the current COVID-19 pandemic will take a global effort, and this agreement is an important example of how we can begin to address this significant challenge through collaborative research.

Stanley C. Erck, President and Chief Executive Officer of Novavax said

We are honoured to partner with the UK government to supply our vaccine, including antigen manufactured within the UK. Our Phase 3 clinical trial in the UK will be a critical component to assess the efficacy of our COVID-19 vaccine, which in a Phase 1 trial has already demonstrated that it is generally well-tolerated and elicits robust antibody responses greater than those seen in patients who have recovered from COVID-19 disease. We are also delighted to expand our collaboration with FUJIFILM Diosynth Biotechnologies in the UK.

Both projects are the result of further investment from the government, ensuring that the UK can have sufficient COVID-19 vaccine should one be found to be safe and effective.

The government also last month launched the NHS COVID-19 vaccine research registry to enable people across the UK to sign up for information about participating in COVID-19 vaccine clinical trials. Aiming to get 500,000 people signed up by the end of October, this would provide scientists and regulators the assurances they need that vaccines secured are safe and effective for use.

Notes to editors

Janssen's Ad26.COV2.S vaccine comprises a proprietary recombinant, replication defective adenovirus 26 (Ad26) vector containing a transgene of the spike protein of SARS-2CoV designed to induce an immune response including neutralising antibodies against the spike protein to eliminate the virus. Preclinical data published in Nature shows protection against infection including potent and long-lasting antibody and cellular immune responses. The global clinical study being delivered by the government and Janssen will run in parallel with phase 3 clinical trials taking place in the US, which is investigating the effectiveness of a single dose of the vaccine.

Janssen Pharmaceutica NV are one of the Janssen Pharmaceutical Companies of Johnson and Johnson.

Novavax's vaccine comprises a recombinant nanoparticle technology containing an engineered COVID-19 spike protein and the saponin-based adjuvant Matrix-M designed to enhance the immune response and stimulate high levels of neutralising antibodies.

When coronavirus invades the body, the immune system fights back in multiple ways including by producing antibodies to neutralise the virus. These antibodies bind to the spike protein on the surface of the coronavirus and prevent them from entering the cells. For immuno-supressed people who cannot mount an immune response, injections of neutralising antibodies could be used to provide several months of protection.

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 (e.g. cancer and immunosuppressed patients) and front line workers exposed to the virus, as well as a treatment for infected patients in hospitals.

Earlier this month, the UK government and Valneva made a multi-million-pound joint investment in a vaccine manufacturing facility in Livingston, West Lothian, which will be at the heart of efforts to produce a new COVID-19 vaccine. This is in addition to the new Vaccines Manufacturing and Innovation Centre (VMIC) which is currently under construction in Oxfordshire, and the new vaccine manufacturing plant in Braintree, Essex recently acquired by the Cell and Gene Therapy Catapult.

Volunteering for COVID-19 vaccine clinical trials

A new NHS service has been launched 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 large numbers of people to be recruited into trials rapidly 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 <u>Vaccine Taskforce</u> in conjunction with the National Institute for Health Research (NIHR) and the Northern Ireland, Scottish and Welsh governments

Anyone living in the UK can <u>sign up online</u> 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.