<u>Fifth COVID-19 vaccine starts UK</u> clinical trials

- Valneva begins first UK clinical trials for its promising COVID-19 vaccine, being developed in Livingston, West Lothian
- the UK government has pre-ordered 60 million vaccine doses
- follows a multi-million-pound UK government investment in Valneva's manufacturing facilities, boosting its capacity to supply up to 250 million vaccine doses

Valneva has today (Wednesday 16 December) started UK clinical trials for its promising COVID-19 vaccine, currently being developed in Livingston, West Lothian.

Speciality vaccine company <u>Valneva</u>'s candidate will initially be tested on 150 UK volunteers at four <u>National Institute for Health Research</u> (NIHR) testing sites in Birmingham, Bristol, Newcastle and Southampton. These early phase 1 and 2 trials will show whether the vaccine produces a safe and effective immune response against COVID-19.

Should this early trial prove successful, larger clinical trials will be planned for April 2021 with over 4,000 UK volunteers testing 2 doses of the vaccine in 2 groups: those aged between 18-65 years and over 65s.

The UK government has already pre-ordered Valneva's vaccine candidate and should studies prove it to be safe and effective, 60 million doses could be made available to the UK by the end of 2021.

This latest milestone follows a <u>multi-million-pound up-front investment</u> announced in August by the UK government and Valneva to expand its Livingston facility. This supports over 100 highly skilled jobs for technicians and scientists at the West Lothian site, while advancing Scotland's vaccine manufacturing capacity.

Through this investment, if Valneva's vaccine candidate proves successful, this permanent facility will potentially have the capacity to supply up to 250 million vaccine doses to the UK and internationally.

Valneva's vaccine is the fifth to enter clinical trials in the UK, alongside Oxford/AstraZeneca, Imperial College London, Novavax and Janssen, whose studies are currently ongoing.

Business Secretary Alok Sharma, said:

As we take the monumental steps in rolling out the first COVID-19 vaccine, we must remember that we need to have a range of vaccines available to protect the British public now and long into the future.

Today we have more welcome news that life-saving clinical trials will begin across the country to test the safety and effectiveness of Valneva's vaccine, which is being clinically developed right here in the UK.

Having visited Valneva's state-of-the art facility in the Summer, I have seen first-hand the incredible work our scientists and researchers are doing to develop this vaccine.

Thanks to significant investment from the UK government, we are doing all we can to ensure our country has the capabilities in place to produce hundreds of millions of doses of this vaccine for the UK, and for those around the world.

Secretary of State for Scotland Alister Jack said:

Today marks an important milestone not only in the UK's fight against coronavirus but for the hundreds of staff at the Valneva facility in Livingston who have worked tirelessly over the last few months to develop this vaccine. This is a great example of the work of Scotland's world-class life sciences sector.

The UK government is doing everything it can to support all parts of the country throughout the pandemic including ordering and paying for vaccines for the whole of the UK. We are investing in Valvena's manufacturing facility in Livingston, supporting hundreds of highly skilled jobs.

With a number of other vaccines in development, this gives us all hope for the months ahead.

The UK was the first country in the world to both procure and authorise the Pfizer/BioNTech COVID-19 vaccine, ordering 40 million doses — enough for around a third of the population. The UK was also the first country in the West to start a mass COVID-19 vaccination programme, which began on 8 December.

In total, the UK government has developed a portfolio of 7 different vaccine candidates and secured access to 357 million doses to date, putting the UK in the best position for a vaccine and increasing chances of finding vaccines that work for different people.

Chief Executive Officer of Valneva Thomas Lingelbach said:

Our teams have been working extremely hard to develop our differentiated vaccine candidate and I would like to thank them, as well as the UK government, for their dedication and support. While conducting our first clinical trials, we are already ramping-up our manufacturing capacities and commencing production at full-scale so

that we can make the vaccine widely available across the world assuming the vaccine is safe and effective.

Interim Chair of the government's Vaccines Taskforce Clive Dix:

Huge progress has been made in developing a successful COVID-19 vaccine. While this is very positive, we must remember there is no one size fits all approach, and we need to continue developing different types of vaccine so we can vaccinate the UK population.

We believe that Valneva's vaccine is promising and has the potential to tackle coronavirus now and into the future, which is why we have pre-ordered 60 million doses and are investing to help them expand their UK manufacturing facility. This will not only support them in manufacturing hundreds of millions of vaccines for the whole world but boost the UK's resilience against possible future heath crises.

Chief Investigator for the Valneva study Professor Adam Finn said:

We are really pleased to be initiating this first-in-man phase 1 study in Bristol and continuing it in several other centres across the country in the New Year. This is a more traditional vaccine design than those that have been in the news recently, consisting of the whole SARS CoV2 virus that has been chemically inactivated. This kind of viral vaccine has been in widespread use for 60 years.

Our team will be working hard through the Christmas holiday period to get the first participants enrolled and vaccinated. We are pleased to be adding further to the research already done via the NIHR in Bristol over recent months to test COVID-19 vaccines and we are really grateful to the many members of our community who continue to come forward and volunteer to take part in this important work.

Some of the volunteers taking part in Valneva's clinical trials came through from the <u>NHS Vaccines Registry</u>, allowing the UK public to support the national effort to speed up vaccine research. Over 364,000 people have already signed up to the Registry, with more needed.

Additional information about volunteering for clinical studies can be found by visiting the NHS site to join the NHS Vaccine Research Registry.

The Registry was launched by the UK government in partnership with the NIHR, NHS Digital, the Scottish and Welsh governments and the Northern Ireland Executive in July. It aims 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.

Through the government's Vaccines Taskforce, the UK has secured early access to 357 million doses of 7 of the most promising vaccine candidates, including:

- BioNTech/Pfizer Phase III 40 million doses secured
- Oxford/Astra Zeneca Phase III 100 million doses secured
- Moderna Phase III 7 million doses secured
- Novavax Phase III 60 million doses secured
- Janssen Phase III 30 million doses secured
- \bullet GSK/Sanofi Phase I / II 60 million doses secured
- \bullet Valneva Phase I / II 60 million doses secured, with an option to acquire a further 130 million if the vaccine is proven to be safe, effective and suitable