

Press release: Tuesday 12th January 2021 - For immediate release.

## Two new therapies to be tested in ground-breaking COVID-19 clinical trial

Two new therapies are to be studied in patients as part of the ground-breaking AGILE<sup>1</sup> clinical trial platform, with the hope of finding treatments for people with COVID-19.

The trial is being funded by over £3m of investment from GlaxoSmithKline<sup>2</sup> and Vir Biotechnology<sup>3</sup> who have joined forces with researchers from the Universities of Liverpool and Southampton who are leading early phase trials to test new treatments for COVID-19.

The two monoclonal antibody therapies, VIR-7831 and VIR-7832, will be given to patients who have tested positive for COVID-19 and have mild or moderate symptoms. Pre-clinical studies of these antibody therapies have already demonstrated promising results in combatting coronavirus infections. While VIR-7831 is currently being evaluated in two Phase 3 clinical trials, the AGILE study marks the first in-human trial of VIR-7832.

George Scangos, Ph.D., CEO of Vir Biotechnology, said: "We are pleased to partner with the NHS to evaluate and advance our monoclonal antibodies for the treatment and potential prevention of COVID-19. This study will be critical to our efforts as we work to understand whether the modifications we have made to VIR-7832 increase its potency and stimulate a T cell response. If successful, VIR-7832 would bring treatment benefits and potentially confer a vaccinal effect that could be important for therapy and prophylaxis."

This is the second therapeutic trial within the UK government supported AGILE drug testing platform. This ground-breaking collaboration between the University of Liverpool<sup>4</sup>, Liverpool School of Tropical Medicine<sup>5</sup>, NIHR Liverpool and Broadgreen Clinical Research Facility<sup>6</sup> based at the Royal Liverpool University Hospital, the NIHR Southampton Clinical Trials Unit<sup>7</sup> at the University of Southampton, Lancaster University<sup>8</sup> and the UK Clinical Research Facility Network<sup>9</sup> aims to rapidly identify therapies that have the potential to be used to treat COVID-19 patients and bring them into early phase clinical trials.

Dr. Hal Barron, Chief Scientific Officer and President R&D, GSK, said: "We are proud to being working with the Universities of Liverpool and Southampton to initiate the first-in-human study of VIR-7832. This study underscores our commitment to advancing our COVID-19 monoclonal antibodies across a range of settings from prevention through treatment. We expect initial results from the AGILE study to provide important insights into the use of VIR-7832 early in the course of infection with SARS-CoV-2."

Professor Saye Khoo, Chief Investigator for the trial, said: "A number of monoclonal antibodies are being studied for treatment of COVID-19, each different in its own way. The potential for VIR-7832 to not only bind SARS CoV-2, but also to stimulate the immune system is a unique feature, and we are very keen to study whether this confers any additional treatment benefit'."

Dr Richard Fitzgerald, Director of the NIHR Liverpool and Broadgreen Clinical Research Facility, said: "We are really pleased to be able to take this trial forward in our Clinical Research Facility, an MRHA accredited unit with a vast experience of conducting first-in-human trials, and we are looking forward to expanding this trial into other CRF sites across the UK in the coming months with support from the MRC."

Professor Gareth Griffiths, Director of the NIHR Southampton Clinical Trials Unit, said: "We are incredibly excited to be adding these two new drugs into the AGILE trial platform. The COVID-19 vaccination programme has given everyone hope that we will bring this virus under control, but it will take time. We therefore need to continue to find safe and effective treatments for people who will unfortunately get COVID-19 and the AGILE platform is a major part of this."

The AGILE trial platform was launched in July 2020, and the first treatment in the drug testing platform entered into patient trials in Liverpool in September.

## **ENDS**

For media enquiries please contact Julia Scheiderer, W2O Group.

Email: agiletesting@w2ogroup.com, mobile: +44 785 457 5152

## **Notes for Editors**

- AGILE is an academic clinical trial platform led by the University of Liverpool and the NIHR
   Southampton Clinical Trial Unit, in partnership with researchers from the Liverpool Tropical
   School of Medicine, NIHR Liverpool and Broadgreen Clinical Research Facility and Lancaster
   University. It has been established to enable the rapid clinical evaluation of potential COVID 19 therapeutics across the UK CRF Network. (www.agiletrial.net)
- 2. GlaxoSmithKline are a science-led global healthcare company (www.gsk.com)
- 3. **Vir Biotechnology** are a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. (www.vir.bio)
- 4. The University of Liverpool is an internationally renowned Russell Group university that is a centre for research, knowledge and innovation. Saye Khoo is Professor in the department of Pharmacology and Therapeutics and his research centres on the therapeutics of Infectious diseases. For more information, please visit About Institute of Translational Medicine University of Liverpool
- 5. Liverpool School of Tropical Medicine was the first institution in the world dedicated to research and teaching in the field of tropical medicine. The state-of-the-art facilities continue to develop new drugs, vaccines and pesticides which put them at the forefront of infectious disease research. For more information, please visit <a href="Home">Home</a> | LSTM (Istmed.ac.uk)</a>
- 6. NIHR Liverpool and Broadgreen Clinical Research Facility is a state-of-the-art, purpose-built facility, embedded within the Royal Liverpool University Hospital which also provides specialist equipment, 24-hour emergency coverage and access to the intensive care unit, the CRF offers a safe and regulated environment to perform clinical research trials to the highest possible standards. The unit was the first NHS based research facility in England and Wales to gain MHRA Phase I Accreditation. For more information, please visit Clinical Research Facility Royal Liverpool Hospital (nihr.ac.uk)
- 7. **Southampton Clinical Trials Unit (CTU)** is a National Institute for Health Research (NIHR) supported CTU with expertise in the design, conduct and analysis of multicentre, interventional clinical trials. The CTU is based within the University of Southampton with

- offices at the University Hospital Southampton NHS Foundation Trust Southampton General Hospital site. (<a href="https://www.southampton.ac.uk/ctu/index.page">www.southampton.ac.uk/ctu/index.page</a>)
- **8.** Lancaster University is a collegiate public research university with expertise in adaptive design and analysis of clinical trials, early phase drug development and Bayesian statistics. For more information, please visit Medical and Social Statistics | Lancaster University
- 9. The UK CRF Network collaborates with clinical research facilities and other experimental medicine infrastructure across the UK and Ireland to develop, share and implement excellence in operational practice to ensure the efficient and effective delivery of studies, and drive forward initiatives that improve quality of patient experience.

  (<a href="https://www.ukcrfnetwork.co.uk/">https://www.ukcrfnetwork.co.uk/</a>)