<u>World first coronavirus treatment</u> <u>approved for NHS use by government</u>

- Ground-breaking coronavirus treatment approved for use across the NHS from today
- Government-funded UK trial showed drug saved lives by significantly reducing risk of death in hospitalised patients who require oxygen
- Government ensures drug is available across all NHS healthcare settings and across the whole of the UK with immediate effect

Thousands of lives will be saved in the UK with the government immediately authorising the NHS to use the world's first coronavirus treatment proven to reduce the risk of death.

Dexamethasone, an anti-inflammatory drug, has been immediately approved to treat all UK hospitalised COVID-19 patients requiring oxygen, including those on ventilators, from today.

The drug has been proven to reduce the risk of death significantly in COVID-19 patients on ventilation by as much as 35% and patients on oxygen by 20%, reducing the total 28-day mortality rate by 17%.

Funded by the UK government, via the National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI), the Oxford University UK RECOVERY trial is the first clinical trial anywhere in the world to show a treatment provides significant impact in reducing patient mortality.

The government has taken action to secure supplies of dexamethasone in the UK, buying additional stocks ahead of time in the event of a positive trial outcome. This means there is already enough treatment for over 200,000 people from stockpiles alone.

Health Secretary Matt Hancock said:

I'm absolutely delighted that today we can announce the world's first successful clinical trial for a treatment for COVID-19. This astounding breakthrough is testament to the incredible work being done by our scientists behind the scenes.

From today the standard treatment for COVID-19 will include dexamethasone, helping save thousands of lives while we deal with this terrible virus.

Guided by the science, the UK is leading the way in the global fight against coronavirus — with the best clinical trials, the best vaccine development and the best immunology research in the world.

I want to thank the brilliant scientists at Oxford University, the thousands of patients who took part in the study, and my own team,

led by Professor Jonathan Van-Tam, who has done such a brilliant job driving this work.

The drug has also been added to the government's <u>parallel export list</u>, which bans companies from buying medicines meant for UK patients and selling them on for a higher price in another country. This will protect supply for UK patients by enforcing regulatory action on those who flout the restrictions.

Throughout the pandemic, the government has supported British research with millions of pounds of funding for clinical trials into the most promising and innovative medicines in our fight against this new virus, including £2.1 million for the RECOVERY trial.

This clinical trial is testament to the success we see when government, scientists and the NHS — including 175 NHS trusts across the whole of the UK — work together. With over 177,000 patients enrolled, it's the largest randomised clinical trial anywhere in the world and will continue to trial other medicines, such as azithromycin and lopinavir-ritonavir.

Deputy Chief Medical Officer, Professor Jonathan Van-Tam, said:

The RECOVERY trial is an outstanding example of the UK leading the world with an impressive study capable of delivering robust answers to critical questions. Although these data have not yet been peer-reviewed.

The positive findings on dexamethasone follow the disappointing findings on hydroxychloroquine. Together these 2 results illustrate the power of properly conducted clinical trials and the inherent danger of assuming things work without robust data.

Whilst tempting to do otherwise, it is always better to wait for the evidence. On the dexamethasone findings, this is very encouraging because the signal on reduced mortality applies to many of the patients admitted to hospitals and the drug is comparatively low priced and available worldwide.

The UK is a world leader in global science and medicine industries. This British trial will now affect the global response to this pandemic.

This breakthrough has only been made possible through the rigour of world-class and world-leading British life-sciences. The government backed British science from the very beginning of this pandemic and today has proven that this was the right call.

The vital information collected by UK researchers will also be used by other countries to reduce mortality rates worldwide.

The type of drug was initially suggested by the government's expert advisory committee, the New and Emerging Respiratory Virus Threats Advisory Group

(NERVTAG). It was then trialled successfully by RECOVERY.

Support from the NIHR Clinical Research Network (CRN) and letters from the UK Chief Medical Officers and NHS England Medical Director Professor Stephen Powis helped to drive recruitment.

Dexamethasone has been demonstrated to have a clear place in the management of hospitalised patients with COVID-19 who are receiving oxygen.

The RECOVERY trial reported the findings of 2,104 patients randomised to dexamethasone in comparison with 4,321 patients randomised allocated to usual standard of care alone. The trial has reported at a dose of 6 mg dexamethasone once a day for up to 10 days or discharge if sooner. No benefit is seen for patients hospitalised and not on oxygen.

There is a 20% risk reduction of mortality for those on oxygen and 35% risk reduction of mortality for ventilated patients.