New heart disease drug to be made available for NHS patients

- Collaboration to offer cutting-edge new cholesterol treatment to tens of thousands of patients at risk of heart disease in coming years
- In a ground-breaking, in-principle agreement with Novartis, introduction of inclisiran on the NHS following approval has the potential to save up to 30,000 lives over the next 10 years
- Innovative manufacturing research collaboration will position the UK as a world-leading destination to develop cutting-edge treatments

Up to 30,000 lives could be saved over the next decade thanks to a proposed pioneering government collaboration with pharmaceutical company Novartis to tackle heart disease — a leading cause of death in the UK.

The yet to be approved drug inclisiran, a treatment to lower cholesterol, will be studied in UK patients as part of a large-scale NHS clinical trial expected to start later this year. Additionally in a world-first, the drug is expected to be available through a population-level agreement — pioneering a game-changing approach to reducing the risk of heart disease.

Early results from clinical trials suggest that if inclisiran is given to 300,000 patients annually, it could help prevent 55,000 heart attacks and strokes, and has the potential of saving 30,000 lives in the next 10 years.

Heart disease is the world's biggest killer and the second biggest cause of death in the UK, with over 3 million people suffering from atherosclerotic cardiovascular disease and 2 and a half million currently relying on statins to lower their cholesterol. Recent trials have shown inclisiran can halve bad cholesterol in just 2 weeks.

Health and Social Care Secretary Matt Hancock said:

As Health Secretary, I'm determined find ways to save as many lives as possible, and to do my best to stop terrible conditions like heart disease from taking people from their family and friends far too soon.

This partnership is fantastic news and is a huge stride forwards in helping to achieve this. This collaboration has the potential to save 30,000 lives over the next 10 years and is proof that the UK continues to be the world-leading destination for revolutionary healthcare.

I will always help the NHS reach its full potential, and novel and innovative collaborations such as this put patients at the forefront of the most promising medical breakthroughs.

Inclisiran, a bi-annual injection, is expected to be filed for approval as a preventative add-on treatment to statins for patients who have already been diagnosed with cardiovascular disease later this year.

It will also be put through the National Institute for Health and Care Excellence's (NICE) approval programme at the earliest opportunity possible and NHS England will agree a population-level commercial arrangement with the company to make it widely available to patients as soon as 2021.

The agreement will make a significant contribution towards meeting the NHS Long Term Plan commitment to preventing 150,000 cardiovascular deaths over 10 years.

The collaboration between Novartis, NHS England, the National Institute for Health Research (NIHR), and Oxford University represents an innovative approach to tackling major public health issues and positions the UK as a world-leading destination to develop revolutionary medicines.

The innovative collaboration will be announced today (Monday) by the Chair of NHS England Lord Prior at the J.P. Morgan healthcare conference in San Francisco.

Lord Prior, chair of NHS England, said:

This innovative and groundbreaking collaboration could transform the health outlook of tens of thousands of people suffering from heart disease, by bringing together in a unique combination our ability to organise large scale clinical trials, to address highly complex manufacturing issues, and to reach a large population of patients.

It is a great illustration of how the UK Life Sciences Strategy can help both NHS patients and the wider economy, and shows that the UK can be the centre of a dynamic life sciences ecosystem whilst delivering great care.

The collaboration also includes the creation of an industry and academic consortium to improve the efficiency in which the UK can manufacture for this form of innovative medicine.

The unique population health model used by the UK will enable the collaboration to address the needs of patients and health systems that have previously not been able to be met on a large scale. The new cost-effective process will lead the way for innovative approaches to helping meet large-scale, public health concerns.

This highlights the UK as a prime destination to get new medicines to patients faster and more cost-effectively. Its appetite for innovation, unrivalled infrastructure and world-leading joined-up healthcare system offers the opportunity for similar deals to be done for other drug development projects of this scale.

The UK plans to remain at the forefront of the global life sciences industry, giving our NHS and patients faster access to innovative medicines while supporting the growth of the sector.

Novartis CEO Vas Narasimhan said:

Novartis has a unique opportunity with Inclisiran to use innovative population based approaches to open up a new chapter for the treatment of cardiovascular disease, the world's leading cause of mortality and disability.

Novartis is excited to partner with the UK government to leverage innovative models that could potentially lead to generating leading scientific evidence, accelerate access for patients and ensure continuous improvement in manufacturing efficiency and optimization.

Professor Sir John Bell said:

The discovery and development of Inclisiran marks an important change in the approach to pharmaceutical interventions for public health. This program has introduced the use of health care system data from the NHS to dramatically reduce costs by rapidly identifying patient populations through health records.

I am excited by this collaboration which is likely to have farreaching impact on the way population level disease therapies are developed in the life sciences sector.

Professor of Medicine and Epidemiology at the University of Oxford Martin Landray said:

This trial provides an opportunity to demonstrate how a highly streamlined trial can be conducted within the UK by combining elements of patients already diagnosed cardiovascular disease and received treatment through the successful ORION-4 trial with the high-throughput clinics developed for UK Biobank.

The trial will provide both a very reliable test of the efficacy and safety of inclisiran to support a population-health approach to the management of cholesterol, and act as an exemplar for future trials of other treatments in the UK.

- Over the past decade, the pharmaceutical industry has largely stopped finding solutions for large public health issues, such as diabetes, cardiovascular disease and obesity, due to the large costs developing new treatments.
- The UK is paving the way to overcome this by making development, manufacturing and route to market faster, cheaper and more efficient for all parties.
- This deal is an example of how the UK can facilitate large-scale prevention trials by addressing early on, the issues of implementation and manufacturing through research funded by government.
- This inclisiran study is being supported by the National Institute for Health Research (NIHR), the nation's largest funder of health and care research, funded by the Department of Health and Social Care.
- Through the Clinical Research Network, the NIHR supports the planning, set-up and delivery of high quality clinical research with a network of experts across 30 specialties embedded across the NHS across England. Providing £300 million of support each year, NIHR CRN support is available to all studies meeting DHSC criteria, regardless of location, study type, or therapy area. It does this through meeting the costs of additional staff, facilities, equipment and support services and through a vast range of national and local resources that support health and care organisations, staff, and patients and the public to take part in research.
- The current Memorandums of Understanding (MOU), which form the basis of the proposal, were negotiated and signed by The Medicines Company prior to its acquisition by Novartis.

About ASCVD

Atherosclerotic cardiovascular disease (ASCVD) is a leading cause of death worldwide. ASCVD results from a thickening and loss of elasticity in the arterial wall. It is a severe disorder and the leading cause of morbidity (sickness) and mortality (death) in most developed countries. High levels of LDL cholesterol build up on the walls of blood vessels. This buildup is called 'plaque'. As blood vessels build up plaque over time, the insides of the vessels narrow. This narrowing blocks blood flow to and from the heart and other organs and eventually causes heart disease or stroke.

About inclisiran

Inclisiran, potentially the first and only cholesterol-lowering therapy in the siRNA (small-interfering RNA) class, is an investigational twice-yearly therapy in Phase III clinical development. As a siRNA, inclisiran harnesses the body's natural process of RNA interference to specifically prevent production of the PCSK9 protein in the liver, which enhances the liver's ability to remove LDL-C from the bloodstream, thereby lowering LDL-C levels. Inclisiran is not yet approved by the FDA or any other regulatory authority.

Iran: Foreign Secretary's Commons statement, 13 January 2020

Mr Speaker, further to the <u>oral statement on the 7 January</u> by the Defence Secretary, I would like to make a statement on Iran, in response to the urgent question from my honourable friend.

I would first like to express my condolences to the loved ones of those tragically lost on Ukrainian International Airlines Flight PS752. Our thoughts are with all of those affected during what must be a devastating time.

Among the 176 passengers who tragically lost their lives, were 4 British nationals, as well as 82 Iranians.

On the 9 January, we stated publicly, alongside our partners such as Canada and the United States that given an increasing body of information, we believed Iran was responsible for the downing of UIA Flight 752.

Despite the initial denials, the Government of Iran acknowledged on the 11 January that they were responsible.

Now is the time for a full, transparent and independent investigation. This must be a collaborative endeavour, with a strong international component. The families of the victims — including those in Iran — must have answers and must know the truth.

Mr Speaker, the UK is also working with the Canadian-led International Coordination and Response Group, consisting of countries with nationals killed in the plane crash. This group will help with the issuing of visas and the repatriation of the bodies of victims.

Separately, Mr Speaker, Her Majesty's Ambassador to Iran, Rob Macaire, was arrested over the weekend and illegally held for 3 hours.

On the 11 January, the Ambassador attended a public vigil to pay his respects to the victims of Flight 752. He left shortly after arrival when there were signs that the vigil might turn into a protest.

Let me be very clear about this. He was not attending or recording a political protest or demonstration. His arrest later that day, without grounds or explanation, was a <u>flagrant violation of international law</u>.

In response, we today will be summoning the Iranian ambassador to demand an apology and seek full assurances this will not happen again.

Given the treatment of the Ambassador, we are keeping security measures for the Embassy under review.

And we <u>updated our travel advice on the 10 January</u>. As am sure the House will

expect, we currently recommend British nationals do not travel to Iran, or take any flights to, from or within Iran.

On the diplomatic front, in the past week, I have met with our partners in Brussels, Washington and Montreal, including an E3 meeting yesterday evening in Paris.

I have spoken to Foreign Minister Zarif, and the <u>Prime Minister spoke to</u> <u>President Rouhani</u>.

We welcome the overwhelming international support for Her Majesty's Ambassador to Iran, and the rights to which all diplomats are entitled to under the Vienna Convention on Diplomatic Relations.

Mr Speaker, the regime in Tehran is at a crossroads. It can slip further and further into political and economic isolation.

But there is an alternative and the regime does have a choice. The diplomatic door remains open.

Now it the time for Iran to engage in diplomacy and chart a peaceful way forwards.

I commend this statement to the House.

Recognising fraudulent contact about your investments

The Insolvency Service is aware that fraudsters have been contacting investors in insolvent schemes claiming to be from the Official Receiver's office or to have been appointed by the Official Receiver to help recover funds for a fee.

These approaches are always fraudulent.

Official Receivers or any agent legitimately instructed to act on their behalf will never ask you to pay a fee to get some or all of your investment back.

The Official Receiver can only make a return to you as a creditor in failed schemes if it is possible to identify and sell any remaining assets owned by the liquidated company you bought your investment from. All too often businesses of this nature have few if any, assets left to repay creditors and it can take several years to undertake complex asset recovery work and complete a liquidation.

Paying a fee will not make you a priority creditor, meaning you get paid faster or increase the chance of you getting any money back. If you are asked to pay a fee to get your money back someone is attempting to scam you.

If you are asked to pay a fee this will always be a scam. The Official Receiver does not charge investors a fee to get money back and does not employ anyone else to do this on our behalf.

You should <u>report to us</u> all fraudulent contact from individuals stating they can get your lost investments back for a fee. You can also report these approaches to <u>Action Fraud</u>.

The Financial Conduct Authority publishes a list of known fraudulent claims management companies, you can <u>check online if a warning has been posted about the company that approaches you</u>. Just because the company that has contacted you is not on this list does not mean that they are not attempting to scam you.

<u>Finalists announced for the</u> <u>International Tech Hub Network's</u> <u>Female Tech Founders and TeXchange</u> <u>programmes</u>

The International Tech Hub Network has a busy 2020 ahead, delivering delegations and network-wide programmes, and launching Tech Hubs, all whilst continuing to support entrepreneurs around the world who are using technology to solve local development challenges.

Finalists have been chosen for the first two network-wide programmes of the year, Africa-UK: Female Tech Founders taking place this month, and TeXchange, co-delivered with the UK-Israel Tech Hub in February.

Africa-UK: Female Tech Founders

The most ambitious development-focused women tech entrepreneurs from across Kenya, South Africa and Nigeria are coming to London in just over a week's time to participate in the Network's inaugural programme specifically focused on supporting gender inclusive economic growth.

The entrepreneurs will attend the Africa Investment Summit as part of the programme, which has been designed to empower participants with the skills and connections to tackle the existing digital gender gap.

Meet the women driving change across Africa below.

Kenya

Cindy Adem, Village2nation

Village2nation aims to create the largest network of digital hubs cum training centers in rural Sub-Saharan Africa, focusing predominantly on youth in marginalised areas.

Kate Kiguru, Ukall Apps

Ukall Apps develop and deploy apps including Akida, a simple reliable reporting tool, and Uwanjani, an efficient supply chain management app.

Muthoni Masinde, Itiki

ITIKI is a highly accurate drought early warning system that integrates indigenous knowledge and scientific drought forecasting to help small-scale farmers make better informed cropping decisions.

Nyambura Kamau, Viwanda Africa Group

The Viwanda Africa Group offers evidence-based high-impact innovative healthcare technologies; and seeks to accelerate adaptation and maximize efficacy by delivering the right health interventions to the right communities at the right time.

Lucy Njuguna, Nurse in Hand Emergency Response

Nurse in Hand Emergency Response is a social impact technology solution providing aggregated road emergency services, through a web platform, mobile app, wearable devices, AI and IoT technologies.

South Africa

Tebogo Mokwena, Akiba Digital

Akiba Digital is a B2B financial data aggregator with an agnostic data consolidation and enrichment engine that clusters, visualises and predicts consumer behaviour.

Nobukhosi Diamini, Bahati Tech

Bahati Tech offers data protection solutions to help companies comply with data protection regulations and protecting customer sensitive information.

Mandisa Mjamba, Relay Africa

Relay Africa builds modern tech for the healthcare sector to improve service delivery. The first product, Kaadi, is already in use across medical facilities, digitising medical records.

Jaishree Naidoo, Envisionit

Envisionit Deep AI utilizes artificial intelligence to streamline and improve medical imaging diagnosis, to democratise access to healthcare for all.

Tina Fisher, Snapnsave

Snapnsave is South Africa's #1 cashback coupon app that gives shoppers and independent traders cashback when shopping in-store, just by snapping a photo of their till slip.

Nigeria

Keturah Ovio, Limestart

Limestart enables small businesses in Africa's informal sector to transition to the digital economy, by helping them create digital sales transaction records, and enable digital payment methods.

Funmi Adewara, Mobihealth International

Mobihealth International is Africa's 1st fully integrated innovative telemedicine start-up revolutionising access and delivery of healthcare to people in Africa through a low-cost subscription plan.

Damilola Emuze, ScholarX

ScholarX connects high potential students with funding opportunities to help them access quality education.

Ifeoma Hope Uddoh, Shecluded

Shecluded is a financial inclusion company that is focused on providing women with access to credit, financial education and advice to help them achieve sustainable growth in their career and business.

Damilola Olokesusi, Shuttlers Mobility

Shuttlers' platform enables professionals to share rides in corporate buses to and from work, at 60-80% lower cost than ride-hailing services without surge or peak pricing — this reduces congestion and carbon emissions.

TeXchange

TeXchange is an immersive 3-day programme that opens the UK market to forward-thinking startups and exposes British businesses to some of the world's brightest innovators. The 2020 programme addresses healthcare, offering participants direct access to the UK's top healthcare corporate and government agencies.

For this edition, the UK-Israel Tech Hub's flagship programme has opened to the wider network and will include four startups from Hub countries alongside Israeli participants. Meet the global startups revolutionising the healthtech sector below.

India

Abhishek Shah, Wellthy Therapeutics

Kenya

Anjere Irving Amukasa, Sophie Bot

Nigeria

Morenike Fajemisin, WHISPA

South Africa

Gregory Daus, Scout Technologies

Israel

Vijay Solanki, Binah.ai

Tamir Kessel, Breezometer

Ulrich Muehlner, Docdok.health

Ziv Leinwand, Earlysense

Meirav Naor-Weinstock, IMNA

Itai Katzir, Medial Earlysign

Tal Givoly, Medivizor

Shahar Figelman, Selfit Medical

Hilit Hochman, Sivan Innovation

Nir Tobis, Vaica Medical

Find out more and get involved

- Visit the International Tech Hubs homepage on gov.uk
- Stay up to date and explore how you can get involved by signing up to our newsletter
- Email us at international-tech-hub-network@culture.gov.uk, we'd love to hear from you
- Read more #DCMSTechHubs blogs

New traffic commissioners appointed for the north west of England and for Wales

Gerallt Evans will be the new Traffic Commissioner for the North West of England and Victoria Davies will be the new Traffic Commissioner for Wales.

The Senior Traffic Commissioner, Richard Turfitt, said of their appointments:

I am delighted that Victoria and Gerallt have been appointed to the traffic commissioner team.

They bring with them valuable experience of legal process and regulation, which will be used to great effect in serving the communities of their respective traffic areas.

I genuinely look forward to working with them.

They will be taking up their posts in February 2020.

Gerallt Evans

Gerallt has extensive experience working in the legal profession with over 30 years of experience as a solicitor. For nearly all this time, Gerallt has worked as a prosecutor for the CPS either in Wales or at its London HQ.

Gerallt is currently Deputy Chief Crown Prosecutor with responsibility for all prosecutions in Magistrates Courts in Wales.

Victoria Davies

Victoria has over 25 years legal experience. Since 2010, she has worked as a senior lawyer managing the transport team for the Welsh Government.

Before that, Victoria spent 8 years working for DfT as a senior advisory lawyer for various divisions including for the Road Transport Advisory Division.

Ken Skates AM, Minister for Economy and Transport in the Welsh Government, said:

I welcome the appointment of Victoria Davies as the new Traffic Commissioner for Wales. I look forward to our continued close working with the Department for Transport and the Senior Traffic Commissioner, Richard Turfitt, and his Office as we develop the role and presence of the Traffic Commissioner in Wales.

I am pleased that the new Traffic Commissioner is committed to continuing to improve her Welsh language skills to ensure the provision of a bilingual service to HGV and PSV operators in Wales.

The role of the traffic commissioners

Traffic commissioners are responsible for the <u>licensing and regulation of bus</u>, coach and goods vehicle operators, and registration of local bus services.

Where appropriate, they can call operators to a public inquiry to examine concerns about vehicle and driver safety.

They also deal with professional drivers at conduct hearings.