Press release

New heart disease drug to be made available for NHS patients

The government is collaborating with pharmaceutical company Novartis to launch a clinical trial for new cholesterol treatment.

From: Department of Health and Social Care, Department for International Trade, NHS England, and Office for Life Sciences
Published: 13 January 2020

- 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:

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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.
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> “ 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 far-reaching 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."

Background information

- 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.

Published 13 January 2020

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