

UK Government tackles heart disease with new partnership

- Aims to bring first-in-class cholesterol lowering drug to the UK and made available in a world-first innovative model for a large at-risk NHS patient population
- Unique collaboration to explore large-scale primary prevention trial leveraging NHS infrastructure and digital capabilities, making it faster and more accessible for patients
- UK positioned as a world-leading destination to develop similar, cutting-edge treatments for the rest of the world

The UK Government has announced its intent to pursue an innovative new collaboration with pharmaceutical company Novartis aimed at tackling the major world health challenge of cardiovascular disease, as well as bringing meaningful investment to the UK's world-class life sciences sector. 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.

Cardiovascular disease is the world's biggest killer, as well as the second biggest cause of death in the UK with over three million people suffering from atherosclerotic cardiovascular disease.

The investigational drug inclisiran is currently in Phase III development for secondary prevention patients with expected European Medicines Agency (EMA) regulatory filing in Q1 2020. Upon approval and NICE assessment, the intent is to provide inclisiran through a population-level agreement. Providing inclisiran to this high-risk population could make a significant contribution towards meeting the NHS long-term commitment to preventing 150,000 cardiovascular deaths over 10 years.

In primary prevention patients, the proposal is for inclisiran to be given in a large-scale NHS clinical trial that will be the first in the world to treat such a patient population, evaluating a game-changing approach to reducing the risk of heart disease at population-level numbers of patients.

UK Health Secretary Matt Hancock said:

This deal is a strong vote of confidence in our world-leading life sciences sector that enables all high-risk ASCVD NHS patients to benefit from this potentially gamechanging treatment.

I am committed to helping the NHS reach its full potential, and innovative collaborations such as this puts patients at the forefront of the most promising medical breakthroughs.

Novartis CEO Vas Narasimhan said:

Novartis has a unique opportunity with inclisiran to open up a new chapter in the treatment of cardiovascular disease, the world's leading cause of mortality and disability.

We're confident that innovative approaches like this will enable us to accelerate access timelines, deliver on our broader commitment to generating leading scientific evidence, and ensure continuous improvement in manufacturing efficiency and optimization.

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

Lord Prior, chair of NHS England, said:

This innovative and ground breaking 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 eco system whilst delivering great care.

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 help meet large-scale, population 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 enables 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.

Notes to Editor

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.