NICE approves MS drug developed by University of Cambridge researchers

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A new drug based on decades of research at the University of Cambridge has today been approved by the National Institute of Health and Care Excellence (NICE) for use in people with relapsing-remitting multiple sclerosis. Clinical trials have shown that Alemtuzumab, marketed under the name Lemtrada, reduces disease activity, limits the accumulation of further disability over time and may even allow some existing damage to recover.

The approval has been welcomed by the Cambridge researchers whose work, which started in 1991, led to today's announcement, and by the MS Society.

Professor Alastair Compston, Professor of Neurology and Head of the Department of Clinical Neurosciences at the University of Cambridge, said: "I am delighted that the decision from NICE will make Lemtrada available on the NHS. This brings to a conclusion work involving a number of research groups in Cambridge, stretching back over several decades, which made possible our use of Alemtuzumab in multiple sclerosis. The decision from NICE now provides an opportunity for neurologists to offer a highly effective therapy for patients with multiple sclerosis early in the course of their illness."

Dr Alasdair Coles, Senior Lecturer, also in the Department of Clinical Neurosciences, added: "We are delighted that NICE has supported the EU decision to make this drug available to anyone with active relapsing-remitting MS, without the restrictions invoked on previous drug

approvals. This represents a significant change in the way therapies for MS are approved. We are pleased that we are able to offer patients the choice of this new treatment option."

Lemtrada, manufactured by pharmaceutical company Genzyme, began life as Campath-1H, a drug developed out of research by Professor Herman Waldmann and colleagues in the Department of Pathology at the University of Cambridge which began in 1979. However, the story of Campath stretches even further back to research by Dr César Milstein at Cambridge's MRC Laboratory of Molecular Biology in 1975 to develop monoclonal antibodies – artificially-produced antibodies, a key component of our immune system which rids the body of invading organisms; this work was to win César Milstein and George Köhler the Nobel Prize for Physiology or Medicine in 1984.

Campath-1H was originally developed as an immunosuppressant to prevent the rejection of bone marrow transplants. The original versions of the drug – Campath-1M and Campath-1G – were developed using mouse and rat antibodies; it would take the development of 'humanised' monoclonal antibodies – which replace regions of the animal antibody with human equivalents – for the drug to be successful in humans. This new drug, Campath-1H, was successful at treating two types of blood cancer, lymphocytic leukaemia and non-Hodgkin lymphoma.

Campath-1H was identified as a potential treatment for multiple sclerosis by Professor Alastair Compston, Professor of Neurology and Head of the Department of Clinical Neurosciences, in the late 1980s. Multiple sclerosis is an autoimmune disease in which the immune system begins to attack the body's own healthy nerve cells, stripping away their protective myelin sheath and preventing electrical signals from passing smoothly and quickly between the brain and body. The drug reboots the immune system by first depleting a key class of immune cells, called lymphocytes. The system then repopulates, leading to a modified

immune response that no longer regards myelin and nerves as foreign.

The first MS patient was treated with the drug in 1991 and as evidence began to mount that the drug would be effective, if used to treat people before the disease process had progressed too far, Professor Compston and his colleague Dr Alasdair Coles, who joined the team a few years later, expanded the trials. Eventually, the results of phase III clinical studies, published in 2012, confirmed that the drug is effective both in MS patients who are previously untreated ('first-line' therapy) and those who have already failed another treatment.

As with any medication, however, the drug is not without its side-effects – roughly one third of patients with multiple sclerosis develop another autoimmune disease, mainly targeting the thyroid gland and more rarely other tissues especially blood platelets. The research team is investigating how to identify people who are susceptible to this complication and testing whether the side-effect can be prevented using an additional drug that boosts repopulation of the immune system.

The announcement by NICE has been welcomed by the MS Society. Nick Rijke, Director for Policy & Research, said: "The NICE approval of Lemtrada is a major step forward in the treatment of people with multiple sclerosis. This drug has taken decades to develop, and we applaud the team at Cambridge for all their work in making it a reality. While it's not without risk, it's proven to be a highly effective medicine for people with relapsing remitting MS and we look forward to seeing it made available to those who could benefit."

Provided by University of Cambridge

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