Multi-center trial to test new treatment for chronic cough

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The National Institute for Health Research has today announced its participation in a clinical trial to test a promising new treatment for chronic cough. If approved, this would be the first new cough drug in 50 years and offer hope to the millions of people living with chronic cough for whom few, if any, effective treatments exist.

A cough is considered to be chronic when a patient has experienced coughing for eight weeks or more, with many patients living with the condition for years and even decades without effective treatment. Some patients experience coughing that is so severe it can lead to them vomiting or losing consciousness. While it is not known exactly how many people suffer from chronic cough, it is thought to affect around 12-15 percent of the population.

A new drug which could offer relief to those affected by chronic cough is now being tested by the NIHR Translational Research Partnership (TRP) as part of a twelve week clinical trial. The drug, called AF-219, is being developed by US based biotech company, Afferent Pharmaceuticals. The trial involves 200 patients at 47 sites in the UK and US. Working with the NIHR, Illingworth Research is managing the UK study sites for this trial on behalf of Afferent.

AF-219 works by selectively blocking the P2X3 receptors stopping the mechanism by which certain airway nerves become hyper-sensitized. The drug has already been shown to be effective in reducing cough frequency in several clinical studies, including an initial proof-of-

concept study involving 24 patients, where AF-219 reduced the number of times people coughed by 75 percent compared to placebo.

George Freeman, Parliamentary Minister for Life Sciences, said: "It's fantastic that the Government's NIHR is testing this promising new treatment that could help the millions of patients suffering from distressing chronic coughs. Through our commitment to investing £1bn every year in the NIHR during this Parliament, we're funding world class medical breakthroughs which can help NHS patients and avoid unnecessary NHS treatment costs."

NIHR TRP study lead Professor Jaclyn Smith, from the Centre of Respiratory and Allergy at the University of Manchester, said: "We are just beginning to understand how the nerves in the airways are involved in pathologic cough such as chronic cough. With recent developments in the technology to effectively measure coughs and this important new drug, we have started to see real progress in this area."

The trial will use a cough monitor that was developed by Professor Smith and her team at University Hospital South Manchester and the University of Manchester in collaboration with UK SME Vitalograph and supported by the NIHR South Manchester respiratory and allergy Clinical Research Facility. The VitaloJAK works by recording the cough sounds and allows the number of coughs in a 24-hour period to be counted and the effects of new therapies to be objectively quantified.

Professor Smith said: "Previously, studies relied on patient reported outcomes, which are not always reliable. This may lead to effective drugs being dismissed due to inaccurate reporting and, I believe, is a contributing factor to the lack of interest from big pharma companies in investigating new cough treatments. For the first time, we have a new drug for which we will be able to demonstrate reliably whether it can reduce coughing in our patients."

Patient recruitment is now underway and is due to complete in the next two months. The trial is the first commercial clinical trial in the UK to use the Health Research Authority's new approval system. HRA approval simplifies the approvals process for research, making it easier for clinical studies to be set up. By bringing together the assessment of governance and legal compliance it replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

John Illingworth, Managing Director of Illingworth Research, the CRO running the program in the UK, said: "We have been privileged to be the first organization to use this new HRA approval process and the positive difference in study timelines has been tremendous as a result."

Mark Samuels from the National Institute for Health Research said: "This could be the first new cough drug in 50 years. This large-scale trial takes us a step closer to being able to treat chronic cough. It offers real hope that this severe condition can be treated."

Provided by NHS