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MULTI-CENTRE TRIAL TO TEST NEW TREATMENT FOR CHRONIC COUGH

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 England’s 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.”

ENDS

Notes to editors:

About NIHR Translational Research Partnerships

NIHR Translational Research Partnerships bring together world-class investigators in the UK’s leading academic and NHS centres to support collaboration with the life sciences industry in early and exploratory development of new drugs and other interventions. Research centres that make up the Partnerships have been selected to work together based on their proven ability to deliver in experimental medicine and translational research. As members of a Partnership, each centre has committed to work with industry through a consistent point of contact provided by the NIHR Office for Clinical Research Infrastructure (NOCRI).

There are currently two NIHR Translational Research Partnerships focusing on one of the following areas:

- Joint and related inflammatory diseases – including rheumatoid arthritis, osteoarthritis, synovitis
- Inflammatory respiratory disease – including asthma, allergy, COPD, cystic fibrosis, acute lung injury, respiratory infection.

For further information, visit www.nocri.nihr.ac.uk

About NOCRI

The NIHR Office for Clinical Research Infrastructure (NOCRI) helps public, charity and industry research funders work in partnership with NIHR infrastructure and to maximise the impact of the Department of Health's £0.5b/year investment in clinical research infrastructure.

Equally, it ensures that NIHR-supported Centres, Units, Facilities and Networks can work together to help drive the flow of innovative research for patient benefit.

NOCRI supports research partners by:

- Research signposting - help with navigating the clinical research environment and finding expert researchers and world class facilities and technologies.
- Research collaboration management - support for the development of collaborative research partnerships.

For further information, visit www.nocri.nihr.ac.uk.

About the NIHR

The National Institute for Health Research (NIHR) is funded by the Department of Health to improve the health and wealth of the nation through research. Since its establishment in April 2006, the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into tangible benefits for patients and the economy, and developed and supported the people who conduct and contribute to applied health research. The NIHR plays a key role in the Government's strategy for economic growth, attracting investment by the life-sciences industries through its world-class infrastructure for health research. Together, the NIHR people, programmes, centres of excellence and systems represent the most integrated health research system in the world.

For further information, visit www.nihr.ac.uk.

About Afferent Pharmaceuticals, Inc.

Afferent Pharmaceuticals, Inc. is a leader in the development of novel, selective drugs for the treatment of a range of debilitating neurogenic disorders. These disorders affect millions of patients who suffer from chronic respiratory and urologic sensory pathologies as well as chronic pain, and who have limited, if any, treatment options. These chronic disorders arise when certain nerve fibers become hyper-sensitized as a result of inflammation, distress, infection or tissue injury, and sometimes remain chronically sensitized for months or even years.

Afferent is developing molecules that selectively block P2X3, a purinergic receptor that plays a key role in the sensitization of these nerves. The Afferent team and scientific advisors represent leading edge expertise in P2X3 biology, discovery and development, and the company's goal is to develop a pipeline of targeted drugs to treat a number of significant

unmet medical conditions, including pathologic cough, resistant hypertension and chronic pain.

About the Illingworth Research

Illingworth Research is a well-established UK based full service Clinical Research Organisation (CRO) with a specialist homecare research nursing solution for clinical trials at home, school or in the workplace. They have expertise in project management, monitoring, regulatory submissions and full service capability in addition to specialist medical photography services and research nursing provision both on site and in patient homes and regularly acts as EU Legal Representative for US Sponsors.

For further information contact:

Ellie Gadd

Communications Manager, NIHR Office for Clinical Research Infrastructure (NOCRI)
Minerva House, 5 Montague Close, London SE1 9BB

Tel: +44 203 794 7370

E-mail: ellie.gadd@nihr.ac.uk

www.nocri.nihr.ac.uk

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