

For immediate release

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Ario Pharma Commences Efficacy Trial of TRPV1 Inhibitor in Chronic Idiopathic Cough

- **Randomised, double-blind, placebo-controlled, cross-over Phase IIa study**
- **Trial being conducted in parallel with study in COPD Cough**
- **Expected to complete during Q4 2014**

Cambridge, UK, 09 July 2014: Ario Pharma Ltd, the biopharmaceutical company developing innovative new treatments for respiratory disease, announced today that it has commenced a Phase IIa study of its oral TRPV1 antagonist, XEN-D0501, for the treatment and prevention of cough in patients with chronic idiopathic cough (CIC).

Approximately 20 patients will be enrolled into the study, which is being led by Professor Jacky Smith (Principal Investigator), University of Manchester and University Hospital Manchester NHS Foundation Trust, and Dr Lorcan McGarvey, Clinical Senior Lecturer, Queens University and Belfast City Hospital, Belfast. Patients with CIC will be assigned to receive XEN-D0501 or a placebo in a randomised, double-blinded, cross-over study.

XEN-D0501, a potent and selective small molecule inhibitor of TRPV1, has successfully completed multiple Phase I studies and been shown to be safe and well tolerated. The frequency of coughing will be assessed in treatment and placebo groups throughout the study, using validated ambulatory cough monitoring technology developed by Professor Jacky Smith.

Dr John Ford, CEO of Ario Pharma, commented: *“Patients with chronic idiopathic cough have a heightened cough reflex which means that their cough is triggered by minor environmental stimuli that would not normally evoke coughing. This neuronal hypersensitivity is mediated through TRPV1 and because XEN-D0501 selectively inhibits TRPV1 it is expected to prevent coughing in this patient group. The study announced today is being conducted in parallel with a second study of XEN-D0501 in patients with cough associated with chronic obstructive pulmonary disease, which is already under way.”*

Jacky Smith commented: *“It is often not appreciated that chronic cough can be a severe problem, ruining sufferers’ lives. These patients may cough between hundreds and thousands of times per day, and treatment options are extremely limited.”*

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Notes to Editors:

About XEN-D0501

XEN-D0501 is a Phase 2 ready drug that inhibits TRPV1, an ion channel known to play a pivotal role in controlling airway vagal sensory nerve activation and the cough reflex. In preclinical studies, XEN-D0501 suppressed ex vivo vagal nerve firing in response to tussive agents and cough counts in animal models. There is substantial published clinical evidence for the role of TRPV1 in the pathogenesis of cough, which suggests that TRPV1 antagonists could inhibit chronic cough in both idiopathic cough and COPD cough (Khalid et al. 2011). XEN-D0501 has demonstrated good oral bioavailability and appropriate pharmacokinetics and been remarkably well tolerated in both healthy volunteers (Round et al. 2011) and patients.

References:

Round P, Priestley A, Robinson J. An investigation of the safety and pharmacokinetics of the novel TRPV1 antagonist XEN-D0501 in healthy subjects. *Br J Clin Pharmacol.* 2011;72(6):921-31.
Khalid S. Cough responses to tussive agents in health and disease. *Thorax.* 2011;66:Supp 4 S139.

About Ario Pharma

Ario Pharma Ltd focusses on the development of drugs for the treatment of respiratory indications. Ario is about to evaluate the anti-tussive properties of XEN-D0501, a potential best-in-class TRPV1 inhibitor, in two Phase 2 clinical trials that will read out in 2014. The company is managed by a highly experienced development team and supported by world-renowned KOLs in respiratory disease. For more information see www.ariopharma.com