



First Phase I Clinical Study Successfully Completed

Novel betahistine nasal spray safe and well tolerated

Melbourne, Victoria (10 February 2015) Otifex Therapeutics, an emerging Australian specialty pharmaceutical company developing a new treatment for the most common cause of acquired hearing loss in childhood, Otitis Media with Effusion (OME or 'glue ear'), has successfully completed the first stage of its clinical development programme.

The Phase 1a study, conducted at two clinical sites in Australia, was a randomised, placebo-controlled, double-blind, 'Single Ascending Dose' clinical trial in healthy male and female adult volunteers, to examine safety, tolerability and drug distribution characteristics. In this first stage of the clinical trials process, volunteers receive a single nasal spray dose, and once safety was established, doses were increased in subsequent groups of volunteers.

The novel betahistine nasal spray was shown to be safe and well tolerated as a single dose in healthy adult volunteers at all the doses tested.

"We are very pleased with the performance of our betahistine nasal spray in our first clinical trial," said Otifex CEO Dr Christopher Wright. "While betahistine tablets have been safely used by over 130 million people worldwide, it was important to demonstrate the safety and tolerability of this novel form of the drug for a new disease indication. Our goal is to develop a safe, easy-to-use alternative treatment to surgery for the many children suffering from OME-related hearing loss. We are now one step closer to realising this goal."

OME is common. In the United States for example, it affects around 5 million young children per year. Many (more than 500,000) are treated surgically with the insertion of tympanostomy tubes, or 'grommets', following a 'watchful waiting' period when the treating physician assesses whether middle ear fluid shows any signs of clearing naturally. There are no treatments available that improve this clearance rate, and so Otifex's strategy is to address this unmet need.

Based on promising preliminary animal data from the University of Melbourne, and a product and clinical strategy developed in collaboration with the Murdoch Childrens Research Institute, Otifex was established in 2009 to develop a betahistine-based product suitable for use in small children. The Otifex product is designed to improve hearing at a critical time in childhood development, and to reduce the need for surgical intervention.

The Company estimates the market for the Otifex product in OME is up to \$1.2b in the United States alone. Otifex has patents covering the use of its betahistine nasal spray product, granted in the United States, Europe, China, Japan, and in other major markets.

The Company is now preparing for the next stage of its clinical programme, a Phase 1b study in a patient population to address repeat dose safety, tolerability and efficacy.

About Otifex Otifex Therapeutics Pty Ltd (www.otifex.com) is an emerging Australian specialty pharmaceutical company developing a new treatment for the most common cause of acquired hearing loss in childhood, Otitis Media with Effusion (OME or “glue ear”). Treating OME often means surgically inserting “grommets” (tympanostomy tubes) to help return middle ear pressure to normal; there are currently no non-invasive alternatives. Otifex is developing a novel nasal spray to make it easier for the ears to ‘pop’, improving middle ear pressure and helping OME resolve naturally. Our product has the potential to be the first effective non-surgical treatment for OME. Otifex was spun out from The University of Melbourne in 2009. In late 2010 the Company attracted seed investment funding from the Medical Research Commercialisation Fund (MRCF) and Uniseed. Otifex formulated its clinical development strategy in collaboration with MRCF member the Murdoch Childrens Research Institute (MCRI).

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About the Medical Research Commercialisation Fund The \$51 million Medical Research Commercialisation Fund (MRCF) is an innovative investment collaboration established in 2007 and managed by Brandon Capital Partners (www.brandoncapital.com.au). The MRCF invests in early stage development and commercialisation opportunities emanating from its member Australian medical research institutes and allied research hospitals, which includes the Murdoch Childrens Research Institute. The MRCF IIF, LP fund is supported by AustralianSuper, StatewideSuper and the Australian Government through its Innovation Investment Fund (IIF) program. The MRCF Collaboration also acknowledges the support of the State Governments of Victoria, New South Wales, Western Australia, Queensland and South Australia. www.mrcf.com.au

About Uniseed Uniseed is a \$61 million commercialisation fund operating at the Universities of Melbourne, Queensland and NSW, with investment capital provided by the three universities and Australian Super, one of Australia’s largest superannuation funds. Uniseed’s mandate is to facilitate the commercialisation of university-generated intellectual property by targeted investment in highly promising technologies. Uniseed has made over 30 investments in technologies arising from its partner universities including Vintela (trade sale to Quest Software Inc) and Fibrotech Therapeutics (trade sale to Shire plc). www.uniseed.com

About The University of Melbourne *The University of Melbourne* enjoys an outstanding reputation with independently published world rankings consistently placing it as a leader in higher education in Australia, the Asia-Pacific and around the globe. Its national and international performance confirms its position, across a broad range of disciplines, as Australia’s leading comprehensive research-intensive university. From its ground-breaking work towards development of the bionic eye, to the individual research projects of its academics and students, it is uniquely placed to respond to major social, economic and environmental challenges. www.unimelb.edu.au

About the Murdoch Childrens Research Institute (MCRI) The MCRI discovers ways to prevent and treat conditions affecting babies, children and adolescents, helping them lead happy, healthy lives, working side by side with the doctors and nurses at The Royal Children’s Hospital. MCRI conducts innovative, world class research into conditions such as allergies, asthma, brain injury, cancer, cerebral palsy, depression, genetic conditions, obesity, premature birth and infectious diseases. The Australian Paediatric Pharmacology Research Unit (APPRU) is located at the Murdoch Childrens Research Institute and The Royal Children’s Hospital and conducts clinical trials in children to investigate the safety and efficacy of prescription drugs and medications typically developed for adults to assess and improve the safety and efficacy of such therapies for children. The unit’s primary focus is always on the quality use of medicines in children. APPRU is a specialised unit and is one of only six other similarly dedicated units worldwide (outside the US). www.mcricri.edu.au