PolyActiva commences its first Phase I clinical trial with potential to improve daily lives of millions of glaucoma patients

Innovative treatment for second most common cause of irreversible blindness goes to clinical trials supported by USD$12m investment from two Australian venture capital firms

Melbourne, Australia: 31 August 2018 - PolyActiva Pty Ltd, a clinical-stage Australian biotechnology company, has recently recruited first patients into its Phase I clinical study designed to show its glaucoma implant is safe and well tolerated.

PolyActiva has used its proprietary polymer prodrug technology to develop ocular implants that, when placed in the eye, provide sustained treatment over a six-month period, compared to current glaucoma treatment where patients often need to administer four eye drops daily. The revolutionary technology could in the future mean millions of people with open-angle glaucoma no longer need to use daily eye drops.

The potential of removing the reliance on the patient to remember to use eye drops, and the associated difficulty in administering them from the paradigm of glaucoma treatment, is being heralded as major potential health breakthrough by ophthalmologists. Several studies have demonstrated that up to 46 percent of patients have been found not to remember to use their drops or administer them poorly[1]. Failure to adhere to treatment can lead to faster progression of glaucoma, one of the most common causes of blindness.

“This product is designed to make the lives of glaucoma sufferers easier by removing the need for daily drop administration and thus improving treatment management,” says PolyActiva CEO Dr Russell Tait. “The implant is designed to deliver treatment for six months after which it will disappear without further intervention. We’re excited about starting our first clinical study and look forward to seeing how our lead candidate performs.”

Glaucoma is the second leading cause of irreversible blindness globally, affecting 2.7 million Americans and is expected to affect approximately 80 million people worldwide by 2020. In the US, more than 120,000 people are blind from glaucoma, accounting for 9 to 12 percent of all cases of blindness. The global glaucoma market is estimated to be valued at over USD$1 billion.

“The major investors, MRCF and Yuuwa Capital, see this technology having a major potential impact on the lives of millions of glaucoma patients globally,” says Dr Chris Nave, Chairman of PolyActiva and CEO of the Medical Research Commercialisation Fund (MRCF). “This innovative drug delivery

[1] Laura E. Dreer, Christopher Girkin and Steven L. Mansberger. Determinants of Medication Adherence to Topical Glaucoma Therapy. J Glaucoma. 2012 Apr; 21(4): 234–240.

technology has further potential applications, such as being used to administer other types of medication, including antibiotics and steroids for cataract surgery patients."

PolyActiva's first clinical candidate is designed to provide a constant daily therapeutic dose of latanoprost free acid for at least 26 weeks, which is the active ingredient of a commonly prescribed glaucoma eye-drop (Xalatan®).

The clinical trial will assess the safety and tolerance of the implant when administered to glaucoma patients. The implant is also designed to biodegrade within 90 days after the treatment period and is capable of being administered in an ophthalmologist's office under a slit-lamp using a custom-designed administration device.

One of the lead investigators, renowned ophthalmologist and cataract surgeon, Dr Nathan Kerr says, "PolyActiva's treatment approach offers significant potential benefits for patients, addressing adherence and improving treatment of this disease. The bespoke administration device is simple to use and intuitive to operate."

The Phase I clinical trial is being conducted under the Therapeutic Goods Administration Clinical Trial Notification (CTN) scheme at the Royal Victorian Eye and Ear Hospital in Melbourne, Australia, through the Centre of Eye Research Australia (CERA). The Phase I clinical trial will see seven glaucoma patients enrolled to evaluate the safety and tolerability of its PA5108 ocular implant, with initial results expected in Q1 2019.

PolyActiva has secured investment funds to date of USD$12m from Australian-based venture capital firms Brandon Capital and Yuuwa Capital.

Further details of the study design can be found on www.anzctr.org.au or www.clinicaltrials.gov

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About Glaucoma

Glaucoma is the second leading cause of blindness worldwide, affecting an estimated 70 million individuals. Increased ocular pressure in the major risk factor for the optic nerve damage that results in blindness. Treatment is designed to reduce the increased ocular pressure. Eye drop therapy is the mainstay of glaucoma treatment however there are two main deficiencies associated with drop therapy - poor patient adherence resulting from the need to administer drops daily for a disease that is asymptomatic and local side-effects resulting from the topical administration of the

drug to the eye. Alternative methods of delivering drugs to the eye are required to increase patient adherence to treatment.

About PolyActiva Pty Ltd

PolyActiva is a clinical-stage biotechnology company focussed on the development of sustained release site-specific drug delivery products. The company has two products under development, the first ocular implant is in phase I clinical trials for the treatment of open angle glaucoma. The second is an antibiotic-based ocular implant currently in preclinical development for the treatment and prevention of endophthalmitis (ocular infection) after ocular surgery. PolyActiva is based in Melbourne, Australia, and has secured venture capital funding from Brandon Capital's Medical Research Commercialisation Fund (MRCF) and Yuuwa Capital.

About the Medical Research Commercialisation Fund (MRCF) and Brandon Capital Partners

Brandon Capital Partners is a venture capital firm that manages the Medical Research Commercialisation Fund (MRCF), Australia and New Zealand's largest life science investment fund, with AU$505 million under management. The MRCF is a unique collaboration between major Australian superannuation funds, the Australian and New Zealand governments, Australian state governments and more than 50 leading medical research institutes and research hospitals. The MRCF supports the development and commercialisation of early-stage biomedical discoveries originating from member research organisations, providing both capital and expertise to guide the successful development of new therapies. The MRCF has supported more than 38 start-up companies to date, 33 of which were founded by the MRCF.

For more information about Brandon Capital Partners, visit www.brandoncapital.com.au

About Yuuwa Capital LP

Yuuwa Capital is a $40M early-stage venture capital firm based in Perth, Western Australia. Yuuwa invests in outstanding opportunities where Yuuwa can provide both capital and expertise to help founders, management and early investors build great companies. Yuuwa invests in early stage companies principally in the areas of Life Sciences and Information and Communications Technology. Yuuwa Capital's formation in 2009 was supported by private investors and also by the Australian Federal Government's Innovation Investment Fund program.

For more information, visit www.yuuwa.com.au.