PolyActiva completes recruitment in key Phase I glaucoma implant safety study. Six-month treatment period demonstrated.

Company receives additional AU$10m to continue clinical development of biodegradable eye implant

July 23, Chicago – PolyActiva Pty Ltd, a clinical-stage biotechnology company and leader in ocular drug delivery, has completed patient enrolment for its Phase I clinical trial to study safety and tolerability of its biodegradable, slow-release ocular implant for the treatment of glaucoma.

PolyActiva's implant has the potential to revolutionise the treatment for millions of glaucoma patients. Current glaucoma treatment requires eye drops to be administered daily, often multiple times each day. Instead the revolutionary implant delivers the medication to the eye for at least 30-weeks without the patient needing to administer drops, and then biodegrades completely, leaving no residue.

Compliance is a major problem globally for patients with glaucoma, with studies showing up to 46 per cent of patients forget to use their drops or administer them poorly[1]. Failure to adhere to treatment leads to faster progression of glaucoma, the second leading cause of blindness.

"The PolyActiva implant is an exciting advance in glaucoma treatment. It is simple to administer, is well received by patients and ensures the glaucoma medication is delivered to the eye continuously, each and every day", says Dr Nathan Kerr, Principal Investigator for the Phase I study.

"To date, our Phase I study has demonstrated that our implant is safe and well tolerated and provides treatment for a six-month period before it biodegrades completely. We have achieved a major step forward in the advance of ocular implants developing the first implant to completely disappear within 6 weeks of the completion of treatment" says PolyActiva CEO Dr Russell Tait. "With recruitment now closed, top-line safety and initial efficacy data from this study will be available by the end of this calendar year."

PolyActiva further announced that it has closed an AU$10m (US$7m) capital raise. The new capital will be used to fund the next clinical study to identify the efficacious dose for the glaucoma implant. Funds will also support the first clinical study with the company's second asset, an ocular implant to prevent endophthalmitis (ocular infection) following cataract surgery. Recruitment for both studies will commence in October 2019. The additional capital has been provided by existing shareholders and associates, including Australian-based investors the Medical Research Commercialisation Fund, managed by Brandon Capital Partners, and Yuuwa Capital.

"Our latest investment will speed the treatment's development so that we can have it available for patients as soon as possible," says Dr Chris Nave, Chairman of PolyActiva and CEO of the Medical Research Commercialisation Fund (MRCF).

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[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.

The innovative drug delivery technology that underpins PolyActiva's two clinical assets has further potential applications, including being used to administer other types of medication to the eye.

The glaucoma implant, Latanoprost FA SR Ocular Implant, is designed to provide a constant daily therapeutic dose of latanoprost free acid for at least 30 weeks. Latanoprost is the active ingredient of a commonly prescribed glaucoma eye-drop treatment (Xalatan®), a product with peak sales of $US1.7bn. The implant is easily administered to the eye in an ophthalmologist's office under a slit-lamp using a custom-designed administration device.

Initial data on the Phase I clinical trial, conducted at the Centre of Eye Research Australia (CERA), is expected to be released in January 2020.

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About Glaucoma

Glaucoma is the second leading cause of irreversible blindness globally, affecting 2.7 million American's and is expected to affect approximately 80 million people worldwide by 2020. In the United States, more than 120,000 people are blind due to glaucoma, accounting for 9 to 12 per cent of all cases of blindness. 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 early clinical 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