



## **PolyActiva Announces Positive Phase IIa Trial Results in Low Dose Cohort for PA5108 Ocular Implant with Prezia™ Sustained Drug Delivery Technology**

*Primary and Secondary Efficacy Endpoints Met, Demonstrating Statistically Significant Reduction in Intra-Ocular Pressure (IOP) for Patients with Glaucoma*

**Melbourne, Australia – February 17, 2022** – [PolyActiva Pty Ltd](#), a clinical-stage Australian biopharmaceutical company focused on developing unique biodegradable ocular implants with sustained drug delivery for patients suffering from ophthalmic diseases such as glaucoma, today announced that the Phase IIa study of its PA5108 Ocular Implant for the treatment of Primary Open-Angle Glaucoma (POAG) met both the study’s primary and secondary efficacy endpoints of at least 20% IOP lowering in its low dose cohort. Results from the study were presented by Russell Tait, PhD, Chief Executive Officer of PolyActiva, at the 11<sup>th</sup> Annual Glaucoma 360 New Horizons Forum in San Francisco, CA.

“The results of the low dose cohort demonstrate that the implant achieves a clinically meaningful IOP-lowering effect,” commented Associate Professor Michael Coote, MD, a leading glaucoma specialist at Melbourne Eye Specialists and a principal investigator of the study. “The PA5108 Ocular Implant with Prezia Sustained Drug Delivery Technology may provide a significant advancement in the treatment of glaucoma with the laudable goal of enabling a constant dose of medication for six months via a safe and effective biodegradable implant.”

The open-label, multicenter, Phase IIa study was designed to evaluate the minimum effective dose of the PA5108 Ocular Implant in patients with mild to moderate POAG across 3 dose cohorts (10 subjects per cohort). Primary and secondary efficacy endpoints include mean diurnal IOP at 12 and 26 weeks compared to baseline, and 8am IOP at 6, 18 and 21 weeks compared to baseline.

### **Topline Phase IIa trial results in low dose cohort:**

- Statistically significant IOP reduction vs. baseline of a >20% IOP-lowering effect ( $p < 0.001$  and  $P < 0.01$ ) across all assessment visits.
- Statistically significant and clinically meaningful mean change in diurnal IOP at 12 and 26 weeks ( $p < 0.001$ ).
- Implant persistence through a minimum of 21 weeks with full implant biodegradation by week 40, over a 4-6 week period.
- Low dose implant shown to be generally well tolerated with no ocular serious adverse events related to product, no endothelial cell loss and no implant movement.

“When I offer treatment to my patients with glaucoma, I am looking for effective IOP lowering solutions that improve adherence to medical therapy. An implant that enables a repeat dose of treatment with a low-dose, constant daily drug release over the course of 20 weeks and is fully biodegradable while being well tolerated is highly desirable,” stated Ike Ahmed, MD, FRCSC, ophthalmologist at the Prism Eye Institute in Ontario, Canada, Assistant Professor at the University of Toronto, and Clinical Professor at the University of Utah. “These data demonstrate that the PA5108 Ocular Implant with Prezia Technology holds the promise to deliver a target profile that allows me to better manage the progression of glaucoma for patients in my clinical practice.”

“We are excited to announce these positive Phase IIa results as they point to the significant benefit the PA5108 Ocular Implant with Prezia Technology may provide to the ophthalmic community and patients suffering from the



effects of glaucoma,” stated Russell Tait. “We look forward to further exploring its beneficial clinical impact as we move to the next phase of our clinical program.”

The PA5108 Ocular Implant employs the proprietary Prezia™ Sustained Drug Delivery Technology to release a constant daily dose of latanoprost free acid and is designed to include attributes not achievable by conventional blend technologies including: zero order drug release and rapid, complete, non-toxic biodegradation soon after the end of treatment. The Prezia Technology is versatile, can be used to deliver multiple drugs in a single implant and is suitable for front and back of the eye delivery.

### **About PolyActiva**

PolyActiva is an innovative clinical-stage ophthalmology company with a unique proprietary polymeric prodrug technology that enables site-specific, precise and controlled drug delivery to the eye. The company is dedicated to becoming a leader in ophthalmic medicine by providing unique biodegradable implants with sustained drug delivery to improve patient outcomes and quality of life.

PolyActiva has two products under development, the first is the Latanoprost FA SR Ocular Implant for which a Phase Ib/IIa clinical trial is underway after the successful completion of a Phase I clinical trials for the treatment of open angle glaucoma. The second product is a Levofloxacin SR Ocular Implant, an antibiotic-based ocular implant, being developed as a treatment to reduce the risk of infection after cataract 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.

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