



PolyActiva reports promising clinical trial results for its 6-month sustained drug delivery, biodegradable ocular implant in glaucoma patients.

- *Melbourne ophthalmology company PolyActiva is developing a unique biodegradable ocular implant that provides 6 months of sustained drug delivery for patients with glaucoma, the second most common cause of irreversible blindness.*
- *The interim Phase 2a results demonstrate a sustained >20% reduction of Intraocular Pressure after 6 months with a favorable safety profile; 8 (out of 17 subjects) successfully dosed with a second implant.*
- *The implant is the first biodegradable ocular implant in development that has the potential to be used safely for repeat dosing.*

Melbourne, 1st November 2023: PolyActiva is a Melbourne-based ophthalmology company developing a novel proprietary drug delivery platform. Today the company reported promising interim results from an ongoing Phase 2a clinical study for its PA5108 Ocular Implant in subjects with mild to moderate glaucoma. This ocular implant is designed to deliver 6 months of latanoprost and to biodegrade, allowing for repeat dosing. In the initial cohort, PA5108 showed a >20% reduction in intraocular pressure (IOP) at 12 weeks and 26 weeks. In a further cohort, the implant's rapid biodegradation profile has also allowed for eight (8) patients thus far to receive a second implant at 21 weeks, providing ongoing, uninterrupted therapy, with no product related adverse effects.

"For ocular implants to ultimately replace daily eye drops for the treatment of glaucoma, they need to be suitable for repeat administration, which has been a principal goal of PolyActiva's development program. Our Phase 2a results indicate we are well placed to meet that objective," says Vanessa Waddell, CEO of PolyActiva.

Treating glaucoma with daily eye drops has been a mainstay of glaucoma therapy, however between 41-90% of patients do not correctly administer their drops after one year. Ineffective treatment and poor adherence can accelerate loss of sight.

"Sustained drug delivery via an implant could reduce the reliance on daily eye drops and ensure that the correct amount of medicine is delivered consistently, every day," Waddell continues. "The implants received by these trial participants were present for 26 weeks before they biodegraded, which gives us confidence that our technology will be able to deliver a long-term treatment option for glaucoma patients. We look forward to continuing our development of this product as we plan for confirmatory trials in the US."

Glaucoma affects over 2.3 million patients in the US and represents a total addressable market of over US\$4.5bn per annum.

PolyActiva will present its interim phase 2a data at the Eyecelerator Ophthalmic Innovation Conference in San Francisco on November 2nd. The company plans to initiate its Phase 2b clinical trial in the US, Australia, and New Zealand in 2024.



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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.

Our mission is to become a leader in ophthalmic medicine by providing unique biodegradable implants with sustained drug delivery to improve patient outcomes and quality of life.

About PolyActiva's Phase 2a clinical study

A phase 2a open label dose escalation study of the Latanoprost Acid Ocular Implant in patients with mild to moderate glaucoma is being conducted in Australia and New Zealand. The primary objectives of the study are to demonstrate the minimum effective dose of implant to achieve a $\geq 20\%$ reduction in intraocular pressure at 12 weeks and to assess the safety and tolerability of the implant. Three subject cohorts were recruited, a low dose cohort (n=10), a mid-dose cohort (n=10) and a repeat dose cohort (n=17). A high dose cohort was not recruited after the efficacy targets were achieved with the low and mid dose implants. All subjects are required to washout their IOP lowering medication prior to receiving their implant. Subjects in the repeat dose cohort receive their first low dose implant on Day 0 of the study and second within 7 days of their week 21 assessment. Patient enrolment has now been completed. Patients are monitored on study until their implant biodegrades and their IOP returns to levels requiring further medication.