

20 November 2020

Fludrocortisone Safety Study in Humans with dry Age-Related Macular Degeneration.

Eye Co is pleased to advise that the Drug Safety Monitoring Board (DSMB), tasked with monitoring the safety of Eye Co's **Phase 1b Safety Study**, has provided clearance to proceed with treatment of patients with dry-AMD at a higher dose. This follows a review of the data relating to the sentinel patient treated at that higher dose. Recruitment for the balance of the study with **Fludrocortisone Acetate** in the treatment of **dry Age-Related Macular Degeneration** (d-AMD) will now proceed.

The first part of the study showed that *Fludrocortisone Acetate* does **not result in increased intraocular pressure (IOP)** in the human eye, a side effect commonly observed with other intra ocular agents including anti-VEGF's. Similarly, there was no evidence of IOP increase in the sentinel patient treated at the higher dose

No other side effects were observed in this patient.

Fludrocortisone Acetate is a potential breakthrough for management of AMD, including Geographic Atrophy (GA) associated with the dry form of AMD.

Chair of Eye Co's Scientific Advisory, **Professor Jan Provis**, said that animal studies clearly show that intraocular *Fludrocortisone Acetate* acts upstream to reduce populations of cells that release the inflammatory protein C3 in the eye, a key indicator for AMD progression. "Limiting amounts of C3 in the eye is the best strategy for preventing AMD progression" she said.

Professor Philip Penfold, Eye Co's Chief Scientist said that C3 production is scaled up rapidly in most AMD cases. Approaches that simply aim to block its actions may be less effective. In animals, treatment with *Fludrocortisone Acetate* reduces IL-6 and CCL2 in the eye which control inflammation, including C3, further downstream.

There are also substantial pre-clinical data indicating that this drug will be effective in other inflammatory/wet retinal diseases.

d-AMD represents a substantial market opportunity as there is currently no registered or available effective treatment for this condition globally. This condition will afflict over 100 million people in the major pharmaceutical markets over the next 10 years

Your sincerely,



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