



Macular Disease Research Update

Summer Edition 2024

We open the research focus of this edition of Vision Voice with an abridged foreword written by MDFA's National Research Advisor, Professor Paul Mitchell AO, which was published as part of our new Research Impact Report.



There is no denying the devastating impact macular disease can have on someone's life and their family. Macular disease limits functional activities such as reading and driving, and progressively causes loss of independence. In many older people this can lead to a premature need for supported care, including nursing home care. Overall, there can be a markedly reduced quality of life, with increasing depression, as vision loss becomes irreversible. As an ophthalmologist, I see this daily in my clinic.

Over the past 20 years, significant advances in AMD treatment include the pivotal development of anti-VEGF (vascular endothelial growth factor) therapies, which have dramatically improved outcomes for people with neovascular AMD. For geographic atrophy (dry AMD), research into gene therapies, complement inhibitors, and stem cell treatments have shown promise.

Improvements in diagnostic imaging, such as OCT (optical coherence tomography) and OCT angiography, have also enhanced early

detection and monitoring, leading to better management and tailored treatment strategies.

Ongoing randomised trials of potential therapies for geographic atrophy are crucial because current approaches to treatment are limited and often ineffective.

Artificial intelligence (AI) is likely to play an expanding role in AMD treatment opportunities in the future, by enhancing diagnostic accuracy through advanced imaging analysis, using datasets to predict disease progression, and potentially to personalise treatment plans and optimise drug delivery.

I have guarded hope for the future, particularly for treatments for geographic atrophy (GA), and advancing technologies using newer artificial intelligence possibilities.

As you read about the inspiring work into macular disease being undertaken by Australia's leading research minds, I hope you will join me in pledging your commitment to fight for sight in Australia.

New macular disease treatments assessed and approved in 2024



It's been a busy year for the Australian Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee, with a number of treatments for macular and retinal diseases being assessed for registration and/or listing on the Pharmaceutical Benefits Scheme (PBS).

On 1 October 2024, Eylea® 8mg (afibercept 8mg) was PBS listed for treating neovascular (wet) AMD and diabetic macular oedema. This high-dose version of the original treatment (Eylea® 2mg) allows a longer time between eye injections, with the same clinical effects. This will help reduce the number of injections needed for eligible patients.

Vabysmo® (faricimab) eye injections were also recommended for PBS listing for macular oedema caused by retinal vein occlusion (where one of the retinal veins becomes blocked affecting vision). Vabysmo® is already PBS-listed for treating neovascular AMD and diabetic macular oedema.

Two new treatments for late-stage dry AMD or geographic atrophy, (pegcetacoplan and avacincaptad pegol), were submitted to the TGA for approval and registration. The assessment for both treatments is ongoing.

If you have any questions about the new treatments, or your treatment options, talk to your eye health professional.

In this issue, we answer your questions about the new treatments for geographic atrophy, and how MDFA is advocating for these on behalf of our community.

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Geographic atrophy – your questions answered

Q: What is geographic atrophy/late-stage dry AMD?

A: Geographic atrophy – also known as dry (atrophic) age-related macular degeneration (AMD) – is a form of advanced or late-stage AMD.

Some people think that there are only two types of AMD, wet or dry. However, AMD is actually classified into three stages: early, intermediate and late AMD. Late-stage AMD can be either neovascular (wet) AMD or atrophic (dry) AMD/geographic atrophy.

Geographic atrophy happens when retinal cells in the back of the eye gradually die (atrophy), leading to patches of 'missing' retina (lesions). As the lesions grow, central vision may be affected.

Some people with late-stage dry AMD may go on to develop the wet (neovascular) form of AMD. It's possible to have both dry AMD and neovascular AMD in the same eye.

Q: Are there any treatments for geographic atrophy?

A: Yes, but they are not currently approved or available in Australia.

The two new eye injection treatments for geographic atrophy are pegcetacoplan (brand name Syfovre™) and avacincaptad pegol (brand name: Izervay™). These two treatments have been approved in America. The European Medicines Agency has not approved pegcetacoplan for

use in the European Union. We are awaiting decisions on both medicines from the TGA in Australia.

Both treatments are delivered as an eye injection, which need to be continued ongoingly, every 25 to 60 days.

Q: Will I be eligible for the new treatments?

A: It is currently unknown who will be eligible for the new treatments, or who will benefit most.

If they are approved and registered by the TGA in Australia, this doesn't necessarily mean that you will be eligible for treatment.

If the treatments are approved, it's important to talk to your ophthalmologist. They will need to determine if you are eligible and weigh up the benefits and risks to see if the treatments are suitable for you.

Q: How effective are the new treatments?

A: The clinical trials assessing pegcetacoplan and avacincaptad pegol found that eye injections every month, or every two months, helped to slow progression of geographic atrophy.^{1,2}

However, while the trials found that treatment can slow progression, neither treatment improved vision.

In addition, the pegcetacoplan trial found that some people experienced serious adverse events after treatment, including developing neovascular (wet) AMD and inflammation in the

injected eye that could further worsen vision.¹

Q: What can I do to prepare for if the new treatments are approved?

A: If you live with late-stage dry AMD, continue seeing your eye health professional as often as recommended.

Continue to have any tests (e.g. Optical Coherence Tomography or OCT) to ensure that the progress of your dry AMD is regularly monitored.

Ask your eye health professional any questions you may have about dry AMD or the new treatments.

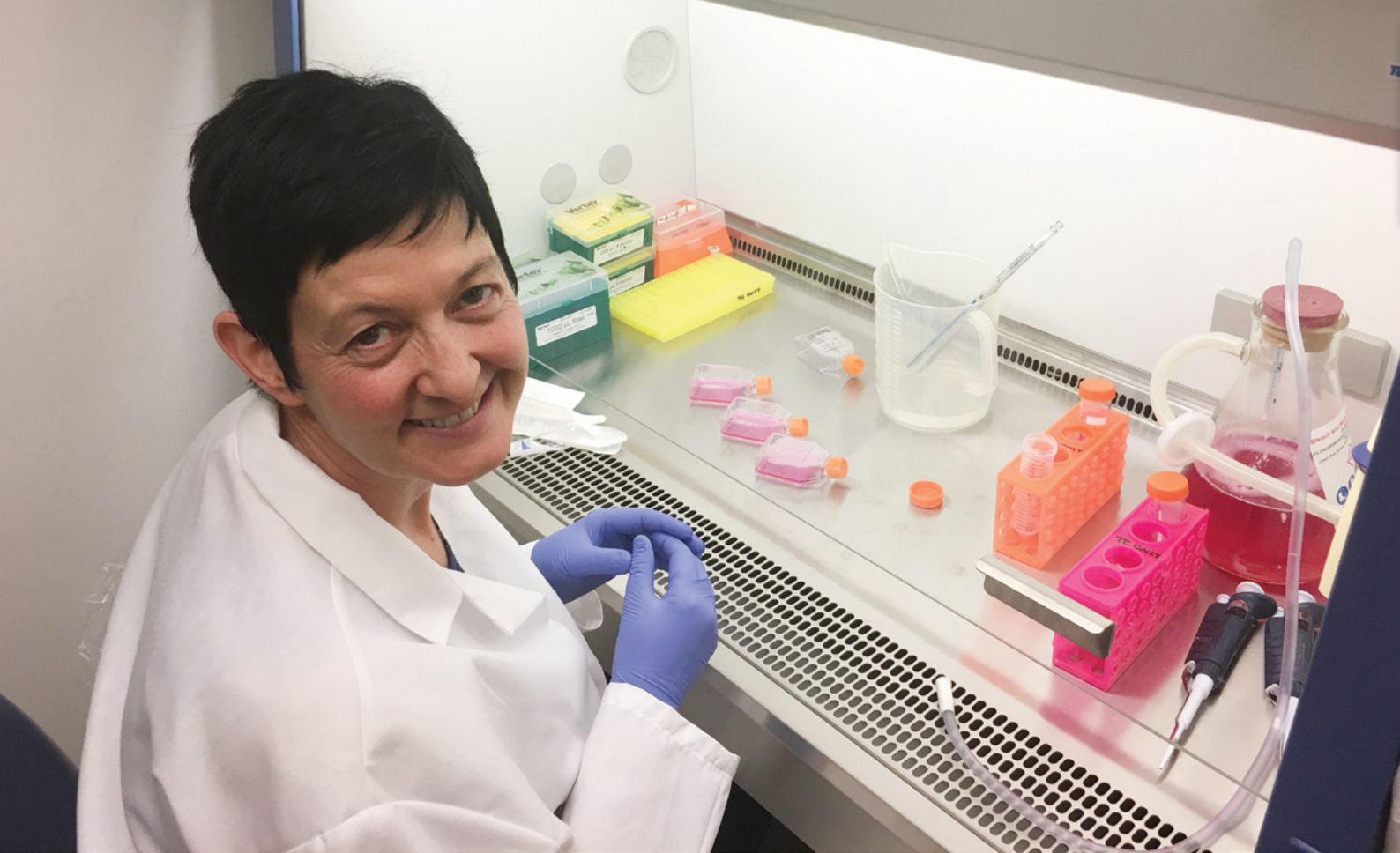
MDFAs advocate to ensure treatments are available quickly and affordably on the Pharmaceutical Benefits Scheme by highlighting the benefits of the treatments to our community and the impacts of delay or lack of access to the treatments.

We actively participate in public consultations for macular disease treatments once they have been approved as safe and effective by the TGA and are being considered for the Pharmaceutical Benefits Scheme.



References

- 1 Heier JS et al. 2023. Lancet; 402: 1434-48.
- 2 Jaffe GJ et al. 2021. Ophthalmology; 128(4):576-586.



Professor Justine Smith, AM.

Exploring new treatments for macular diseases – what does the research future hold?

Exploring innovative ways to treat, preserve or improve sight are the focus of two MDFA-funded researchers, Associate Professor Anai Gonzalez-Cordero and Professor Justine Smith.

Associate Professor Gonzalez-Cordero has made great strides towards developing and testing new treatments by creating a “mini eye” in a laboratory dish by using human stem cells. Cells from the mini eye could potentially be transplanted into the eyes of people with a macular or retinal disease to replace damaged or missing photoreceptor cells. As a double bonus, the mini eye can also be used to identify and test the effects of new candidates for medical treatment.

Professor Justine Smith is investigating existing factors called cytokines to see if they can be used to treat macular oedema, the swelling caused by fluid buildup in the macula that can lead to vision loss. Cytokines – small proteins important for sending signals between cells – help regulate inflammation in the body. But cytokines can also disrupt the movement of fluid away from the retina, causing fluid buildup. Using human eye cells in the laboratory, she is exploring the effect of blocking the action of a particular cytokine called Interleukin 1 β , which could help stop fluid buildup, thereby treating macular oedema.

If successful, both potential discoveries could lead to new avenues and pharmaceutical treatments to explore.