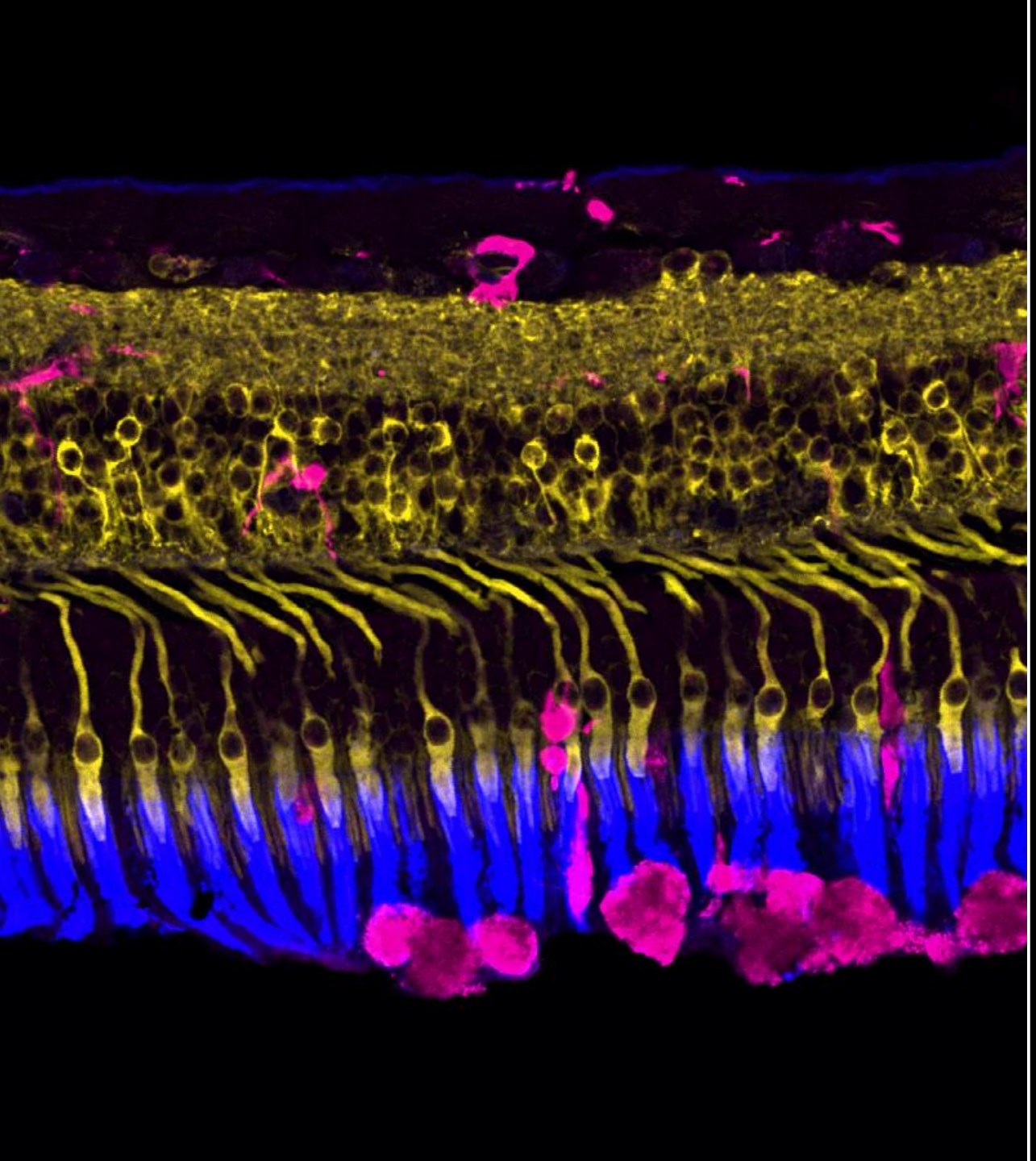

RESULTS OF LEAD CLINICAL TRIAL IN INTERMEDIATE AMD

INVESTOR PRESENTATION

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21 SEPTEMEBER 2018

2RT ellex

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Contents

Overview of LEAD Clinical Trial

The LEAD trial has validated the safety and efficacy of Ellex 2RT® as an intervention for many people with intermediate AMD.

- Double-masked, randomised, sham-controlled trial over 36 months in 292 patients with iAMD across six sites with 1:1 randomisation to Ellex 2RT® or sham treatment received at six monthly intervals[1]
- Primary endpoint – progression to advanced AMD in treated eye of Ellex 2RT® pts versus sham patients
- Secondary endpoints – safety, change in drusen volume and visual function, progression to advanced AMD innon-study eye
- Sub Group – *post hoc* analysis on patients without coexistent reticular pseudodrusen (RPD) deposits representing 76% of enrolled patients versus 24% with RPD at baseline
- Largest ever randomised study conducted in iAMD patients with a non-thermal, non-invasive pulse laser intervention
- First randomised study in iAMD to utilise modern multi-modal imaging (MMI) techniques to detect and define AMD and greater power to detect treatment effects (e.g. OCT, NIR, FAF and CFP)[2]
- Rationally designed following successful pilot study in 50 patients published in 2013[3]

[1] Guymer RH, et al. Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. Ophthalmol 2018; In press
[2] OCT – optical coherence tomography; NIR- near infrared imaging; FAF – fundus autofluorescence; CFP - colour fundus photography
[3] Guymer RH, et al. Nanosecond-laser application in intermediate AMD: 12-month results of fundus appearance and macular function. Clin Exp Ophthalmol 2014; 42(5): 466-79

Overview of iAMD

AMD ("Age-Related Macular Degeneration"):

- leading cause of blindness in the developed world
- affects one in seven Australians over the age of 50[1]

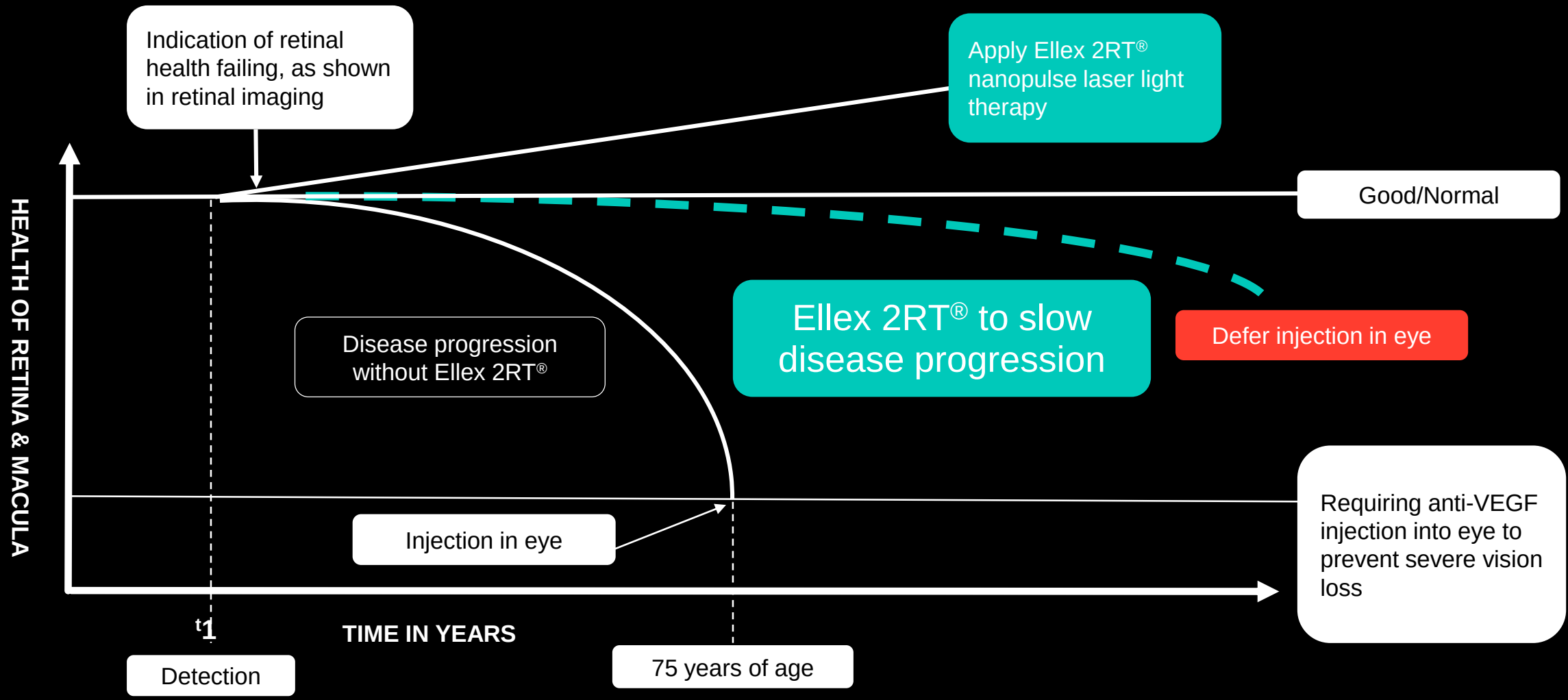
Unmet need: late stage AMD is treated with 6 weekly injections of drugs directly into a patient's eye. This can help to preserves vision, but long-term people lose vision due to scarring. Further:

- onerous on patients and caregivers, and;
- burden for government health schemes to purchase the drugs

1. Macular Disease Foundation, Access Economics

iAMD AND THE LEAD TRIAL

- One of the goals of the LEAD trial was to examine whether Ellex 2RT® could delay iAMD to more advanced forms of the disease, where retinal function declines markedly and vision becomes impaired.
- Treatments for late AMD are limited to regular injections of anti-VEGF drugs to the back of the eye.


Indication of retinal health failing, as shown in retinal imaging
Apply Ellex 2RT® nanopulse laser light therapy
Good/Normal
HEALTH OF RETINA & MACULA
Disease progression without Ellex 2RT®
Ellex 2RT® to slow disease progression
Defer injection in eye
Injection in eye
Requiring anti-VEGF injection into eye to prevent severe vision loss
t1
TIME IN YEARS
Detection
75 years of age

Overview of Ellex 2RT®

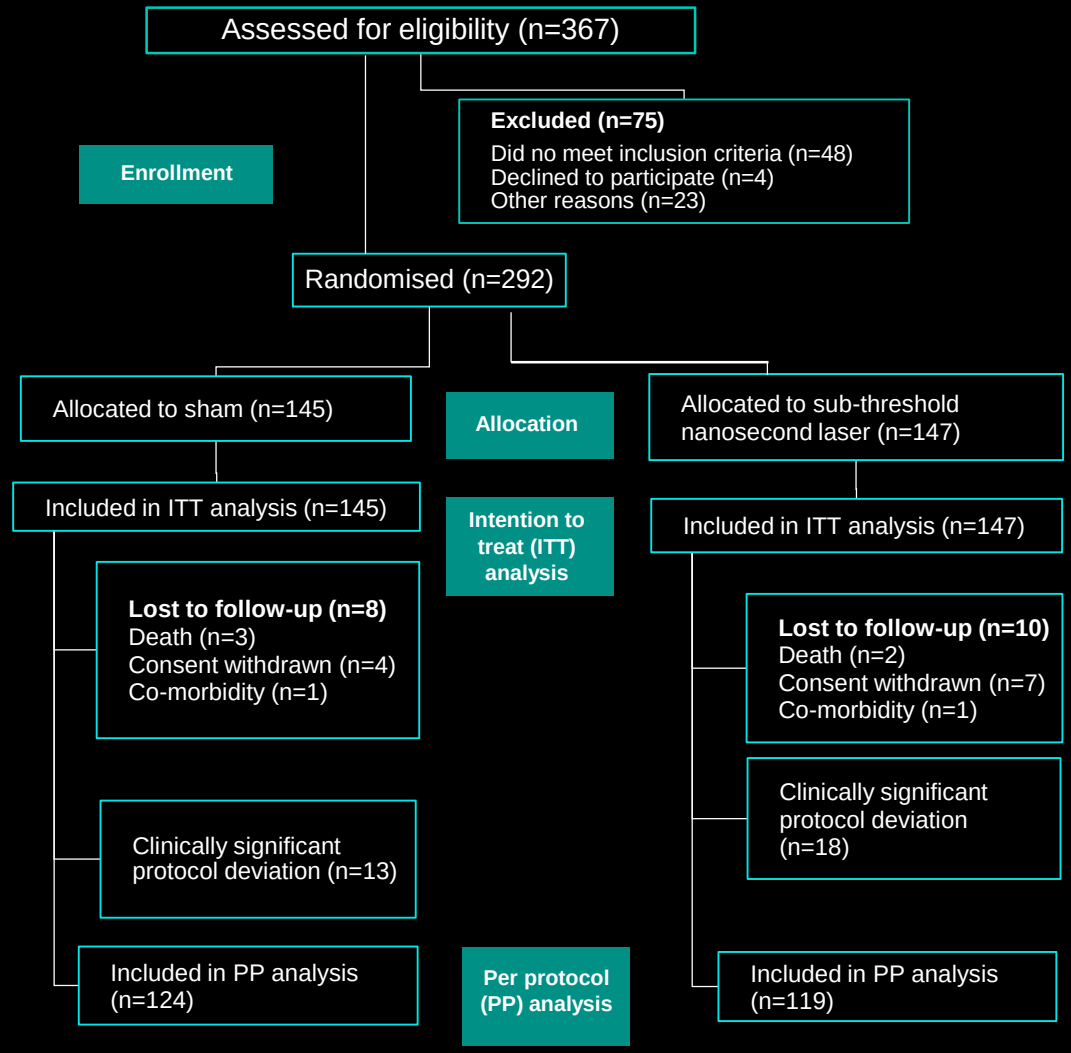
Ellex 2RT® is Ellex's proprietary, patented laser therapy that stimulates the eye's natural healing response to treat the early stages of AMD.

- Specially designed rapid nanosecond pulse, non-thermal laser intervention targeting selected retinal pigment epithelium (RPE) cells to promote extracellular repair mechanism and rejuvenation of the retina
- Technology underpinned by a significant patent portfolio until 2035
- CE Mark for Diabetic Macular Edema (DME) in 2012 and early AMD in 2014
- FDA Clearance for Clinically Significant Macular Edema (CSME) in 2013
- Limited installed base to date; clinicians awaiting further clinical evidence from LEAD trial
- First of Ellex's laser platforms to incorporate per procedure fee software

ELLEX 2RT® LASER

Consort Diagram

- 79.6% of patients assessed were randomised into trial
- Intent-to-Treat (ITT) analysis on 292 patients
- Protocol deviations/lost to follow up of 14% in sham group versus 19% in 2RT® treatment group
- Per protocol (PP) analysis on 243 patients



Patient Baseline Characteristics

- Patient baseline demographics and baseline ocular characteristics were well balanced between the two ITT arms
- No significant difference in each of the baseline characteristics noted (p>0.05), with exception of Lutein-Vision intake higher in sham treatment arm[1]

[1] Lek JJ et al. Subthreshold Nanosecond Laser Intervention in Intermediate Age-Related Macular Degeneration: Study Design and Baseline Characteristics of the Laser in Early Stages of Age-Related Macular Degeneration Study (Report Number 1). *Ophthalmology Retina* 2017

	SNL treatment (n=147)	Sham treatment (n=145)
Demographics		
Age (years)	70·3 (7·0)	69·8 (8·1)
Sex (female)	103 (70·1%)	112 (77·2%)
Ethnicity (Anglo-Saxon)	134 (91·2%)	128 (88·3%)
Smoking history		
Never	77 (52·4%)	77 (53·1%)
Past or current	70 (47·6%)	68 (46·9%)
Macu-Vision®* intake (yes)	50 (34·0%)	45 (31·0%)
Lutein-Vision®# intake (yes)	9 (6·1%)	24 (16·6%)
Study eye ocular characteristics		
BCVA (number of letters)	83 [80, 87]	84 [79, 88]
Pigmentary abnormalities		
Definitely present	46 (31·3%)	51 (35·2%)
Absent or questionable	101 (68·7%)	94 (64·8%)
Reticular pseudodrusen		
Definitely present	35 (23·8%)	35 (24·1%)
Absent or questionable	112 (76·2%)	110 (75·9%)

Data are frequency (%), mean (standard deviation) or median [25th to 75th percentile]. SNL = sub-threshold nanosecond laser. BCVA = best-corrected visual acuity. * = active ingredients of Macu-Vision® include Vitamin C, Vitamin E, zinc oxide, cupric oxide. # = active ingredients of Lutein-Vision® include Lutein, Selenomethionine, Zeaxanthin, omega-3 triglycerides-fish oil.

***Table 1*: Demographics and baseline ocular characteristics**

Safety

- Ellex 2RT® was well tolerated with no statistically significant difference in Serious Adverse Events (SAEs) reported
- Ocular Adverse Events (AEs) with Ellex 2RT® were retinal haemorrhages that resolved in all cases without any untoward sequelae
- All other adverse events recorded were statistically no different between the Ellex 2RT® treatment group and sham group
- 3.4% of patients reported after-images >1 day after treatment
- No difference between the groups in events unrelated to the progression to late AMD

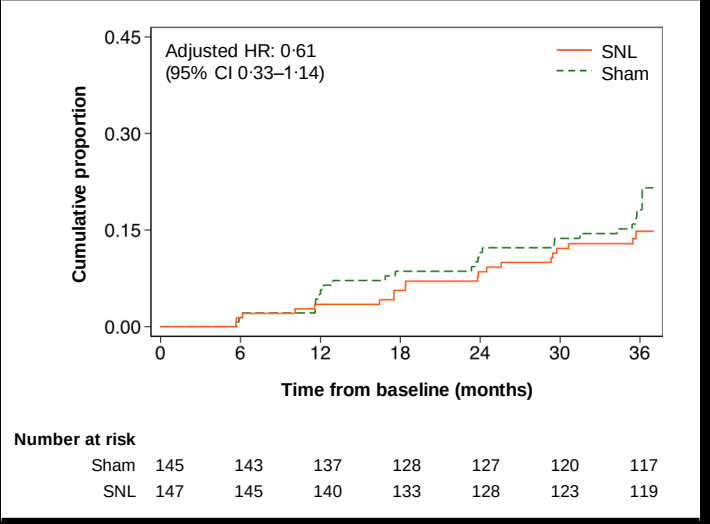
	SNL treatment (n=147)	Sham treatment (n=145)
Definitely related ocular adverse events		
Participants reporting one or more adverse events	15 (10·2%)	1 (0·7%)
After-images*	5 (3·4%)	1 (0·7%)
Retinal haemorrhage	10 (6·8%)	0 (0·0%)
Possibly related ocular adverse events		
Participants reporting one or more adverse events	25 (17·0%)	24 (16·6%)
Epiretinal membrane	1 (0·7%)	4 (2·8%)
Symptomatic PVD or floaters	8 (5·4%)	5 (3·4%)
Ocular discomfort following treatment	7 (4·8%)	11 (7·6%)
Cataract requiring surgery	3 (2·0%)	2 (1·4%)
Other	3 (2·0%)	5 (3·4%)
Other adverse events		
Unrelated ocular adverse events	81 (55·1%)	70 (48·3%)
Non-ocular adverse events	103 (70·1%)	109 (75·2%)
Serious adverse events		
Participants reporting one or more serious adverse events	56 (38·1%)	50 (34·5%)
Cardiovascular or cerebrovascular disorders	14 (9·5%)	13 (9·0%)
Death (unknown cause)	0 (0·0%)	1 (0·7%)
Infections	8 (5·4%)	2 (1·4%)
Injury and procedural complications	10 (6·8%)	9 (6·2%)
Neoplasms (benign and malignant)	7 (4·8%)	8 (5·5%)
Nervous system disorder	3 (2·0%)	3 (2·1%)
Respiratory disorder	5 (3·4%)	3 (2·1%)
Surgery and medical procedures	7 (4·8%)	5 (3·4%)
Other (medical)	23 (15·6%)	22 (15·2%)

Data are number of participants (%). PVD = posterior vitreous detachment. * = visible for more than one day, as reported at the one-week phone call after the initial treatment.

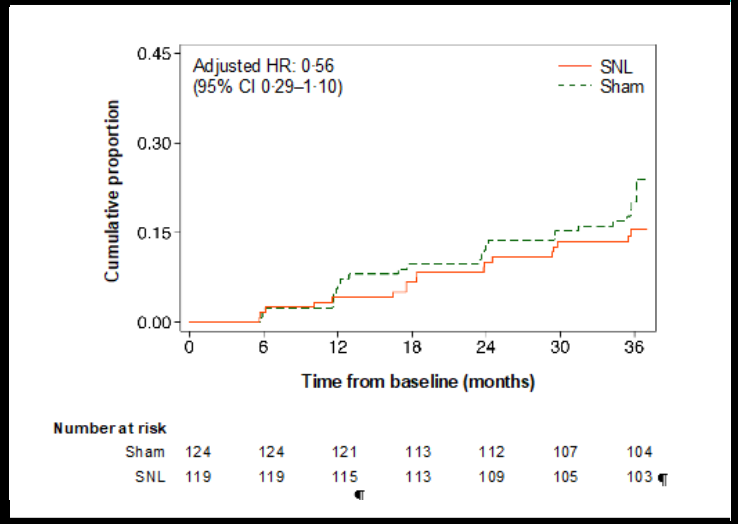
***Table 2*: Number and proportion of patients with adverse events**

Primary Endpoint Results

INTENT TO TREAT (ITT)



PER PROTOCOL (PP)

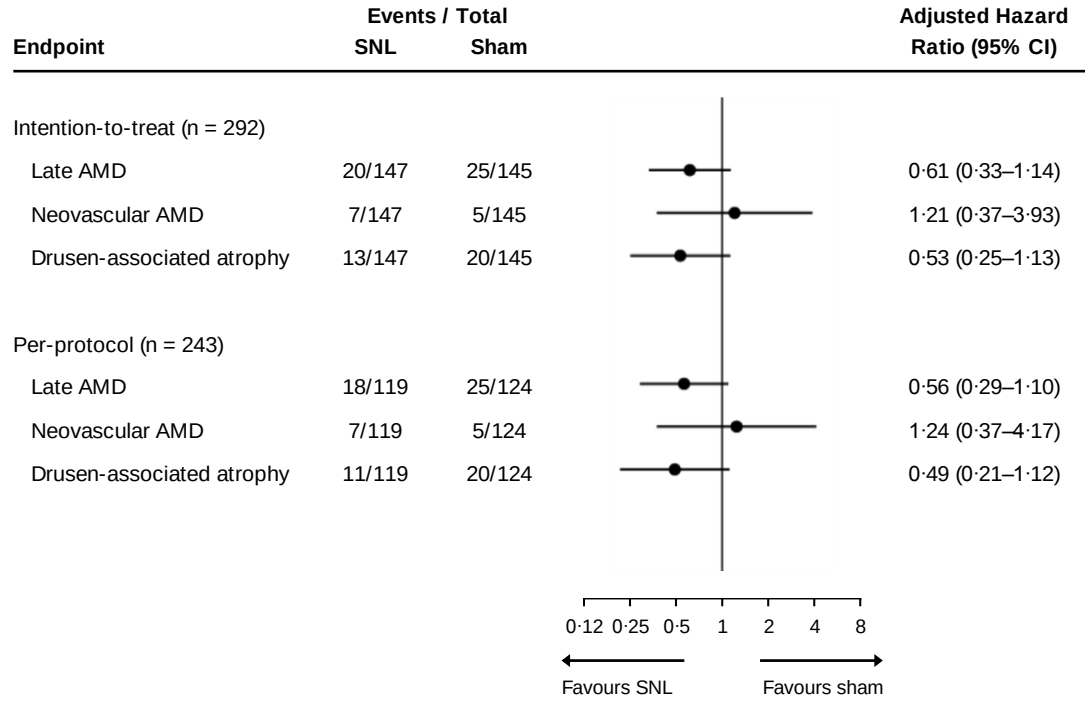


- No significant difference in progression to late AMD under ITT analysis (p=0.122) or the PP analysis (p=0.092)
- At 36 months, 13.6% progressed to late AMD in the 2RT® treatment group versus 17.2% in the sham eye (ITT)
- At 36 months, 15.1% progressed to late AMD in the 2RT® treatment group versus 20.2% in sham eye (PP)
- Non-significant trend in favour of the 2RT® treatment group

* **Adjusted Hazard Ratio (HR)** - The potential confounders of baseline age (as a continuous measure), sex, intake of Lutein-Vision® or Macu-Vision® at baseline (yes vs. no for each), presence of RPD and pigmentary abnormalities (definitely present vs. absent/questionable) were additionally included as covariates in a fully adjusted model as specified *a priori*

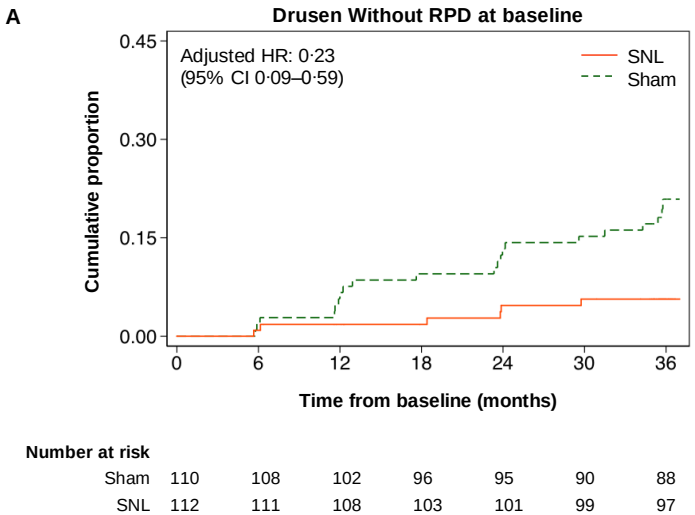
Treatment Effect on Late AMD

- Estimated effect on Forest plot of 2RT® examining the two phenotypes of late AMD (neovascular AMD and drusen-associated atrophy)
- Pronounced treatment effect on drusen-associated atrophy favouring 2RT® (HR=0.53)

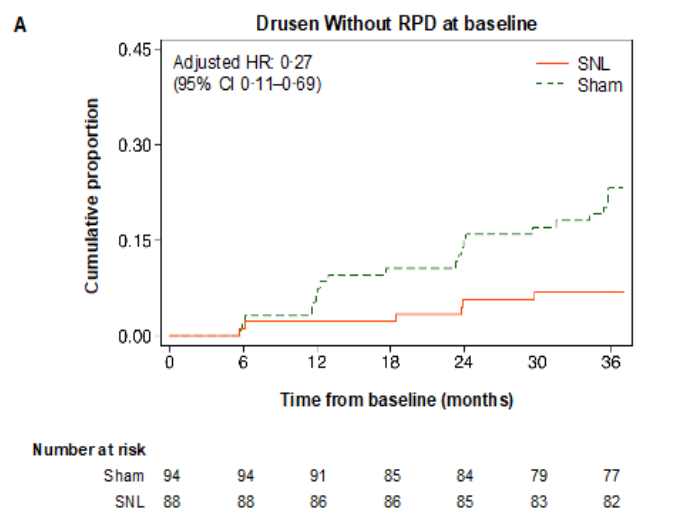


Patients without RPD at Baseline - Analysis

INTENT TO TREAT (ITT)



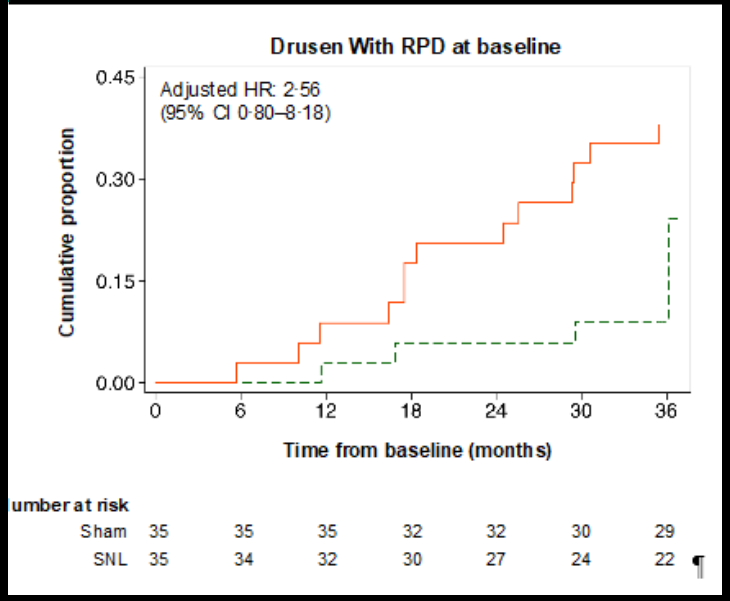
PER PROTOCOL (PP)



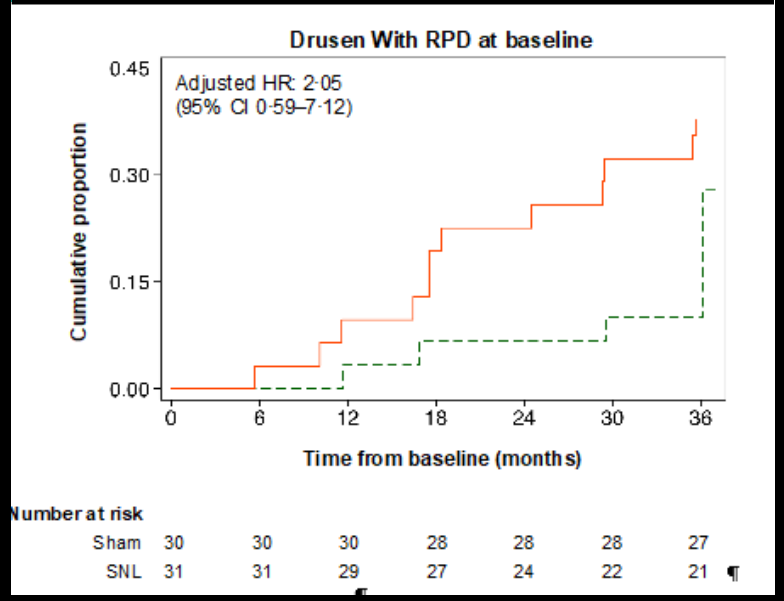
- A clinically meaningful 77% reduction in the risk of progression (HR=0.23) in patients who received 2RT® versus sham
- 2RT® showed a significant treatment effect in this patient population (p=0.002)
- RPD is a key biomarker of retinal pigment epithelium (RPE) dysfunction and has a high association with progression to late-stage AMD
- The 76% of patients without baseline RPD enrolled in LEAD approximates incidence rates in prospective studies, thereby representing a large, clinically important group with no treatments currently approved

Patients with RPD at Baseline - Analysis

INTENT TO TREAT (ITT)



PER PROTOCOL (PP)



- Increased rate of progression to late-stage AMD in the 2RT® treatment group compared to the sham treatment group, although the treatment effect was not significant (p=0.112 for ITT and p=0.258 for PP analysis)
- Ellex 2RT's mechanism of action requires the selective loss and subsequent healing of the RPE, there may be a stage of AMD disease whereby RPE integrity is so greatly compromised as to render treatment with Ellex 2RT® is unsuitable
- Such data is clinically valuable in selecting patients who are likely to respond to Ellex 2RT®

LEAD Trial Conclusions

- Though the primary endpoint across the entire study cohort was not met, Ellex 2RT® displayed an exceptional safety profile
- Patients with no reticular pseudodrusen (RPD) deposits at baseline had a 77% reduction in the risk of progression to late stage AMD at any stage during the trial, which was conducted over three years
- This result is highly clinically meaningful and showed a remarkable treatment effect
- RPD negative sub group represents approximately 75% of all iAMD patients with bilateral large drusen and no geographic atrophy
- LEAD was the first ever trial to show significant efficacy in an iAMD population
- Important new clinical information to guide retinal specialists in patient selection towards those without evidence of RPD
- Results are applicable only to Ellex 2RT® – authors discourage extrapolation of results to other thermal or non-thermal lasers

Market Dynamics and Commercial Opportunity

- Publication in *Ophthalmology*, the most important peer-reviewed ophthalmology journal globally, underscores the significance of the clinical results[1]
- Where Ellex 2RT® is approved for AMD, these markets represent an addressable market of 15 million patients per annum for screening and then treating those early stage patients without detectable RPD[2]
- Addressable market similar in size (patients) to late stage ‘wet’ AMD
- Ellex's commercialisation plan will be developed based on physician feedback, peer-to-peer educational programs focused on disease diagnosis, patient selection and treatment protocols
- Future regulatory clearances in the US, Japan and China will increase the pool of treatable patients to 25 million per annum[3]
- No currently approved treatments for iAMD – only dietary and lifestyle modifications (a standard that resulted from analysis of the AREDS1 and AREDS2 studies[4,5])
- Therapeutic approvals have been limited to late stage ‘wet’ AMD, which represents the minority of AMD patients
- Ellex intends to explore regulatory requirements for the US market

[1] Guymer RH, et al. Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. Ophthalmol 2018; in press
[2] Marketscope Report August 2017 Ophthalmic Laser Report Table 2 “Global Forecast for AMD in all its Forms“, adjusted for Ellex estimates on RPD patients
[3] 3m in the USA, 6m in China and 1m in Japan
[4] Age-Related Eye Disease Study Research Group. AREDS Report No. 8: A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation With Vitamins C and E, Beta Carotene, and Zinc for Age-Related Macular Degeneration and Vision Loss. Archives of Ophthalmology 2001; 119 (10): 1417–1436.
[5] Age-Related Eye Disease Study 2 Research Group. Lutein + zeaxanthin and omega-3 fatty acids for age-related macular degeneration: the Age-Related Eye Disease Study 2 (AREDS2) randomized clinical trial. JAMA. 2013 May 15:309(19):2005-15

THANK YOU

Q/A SESSION