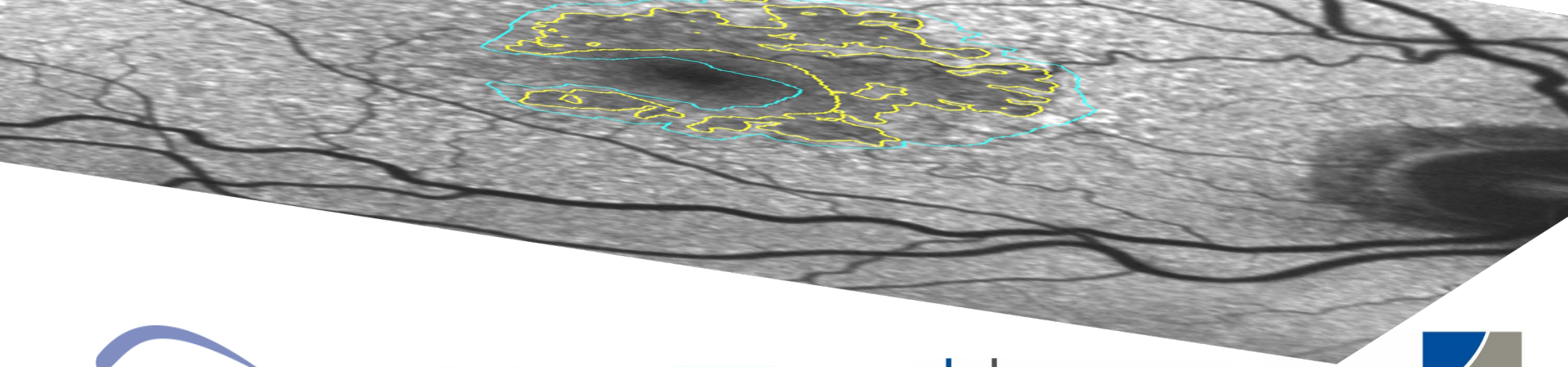


12 Months Interim Safety Results of the Pivotal Study of the PRIMA Retinal Implant System in Patients with Geographic Atrophy: the PRIMAvera Clinical Trial

F.G. Holz, Y. Le Mer, M.M.K. Muqit, L. Olmos de Koo, J. Sahel
for the PRIMAvera Study Group

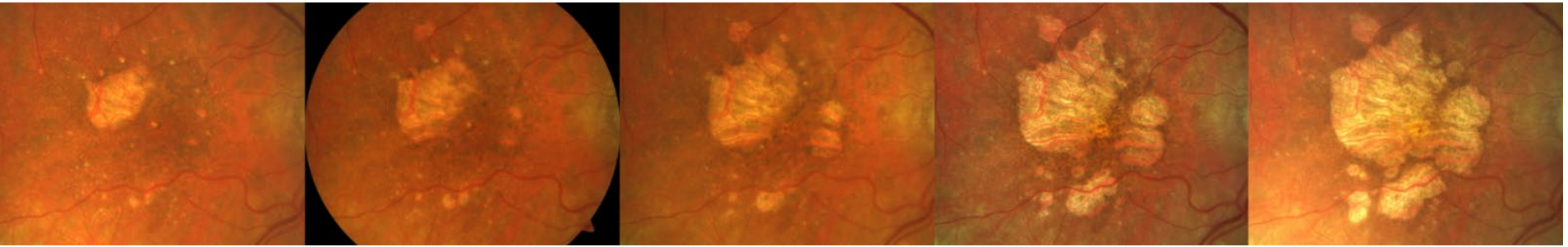
24th Euretina Congress, 20 Sept 2024

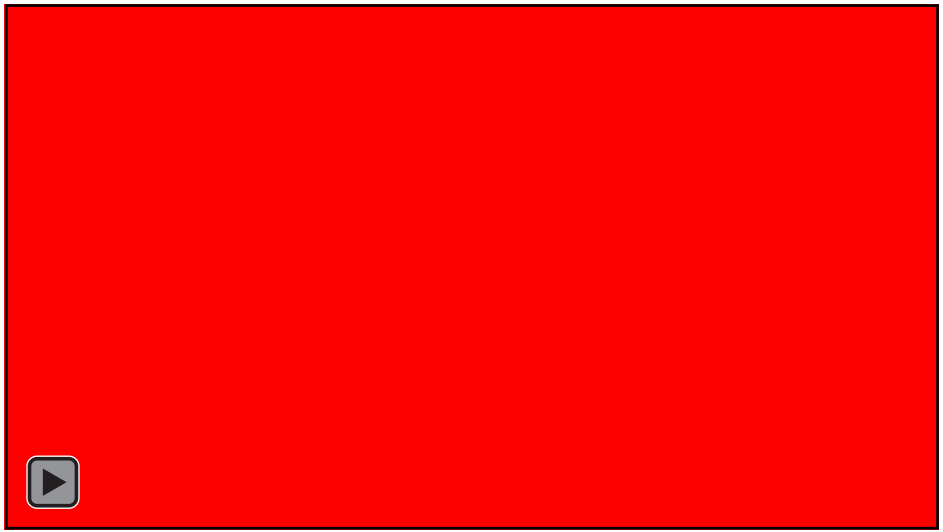
Disclosures

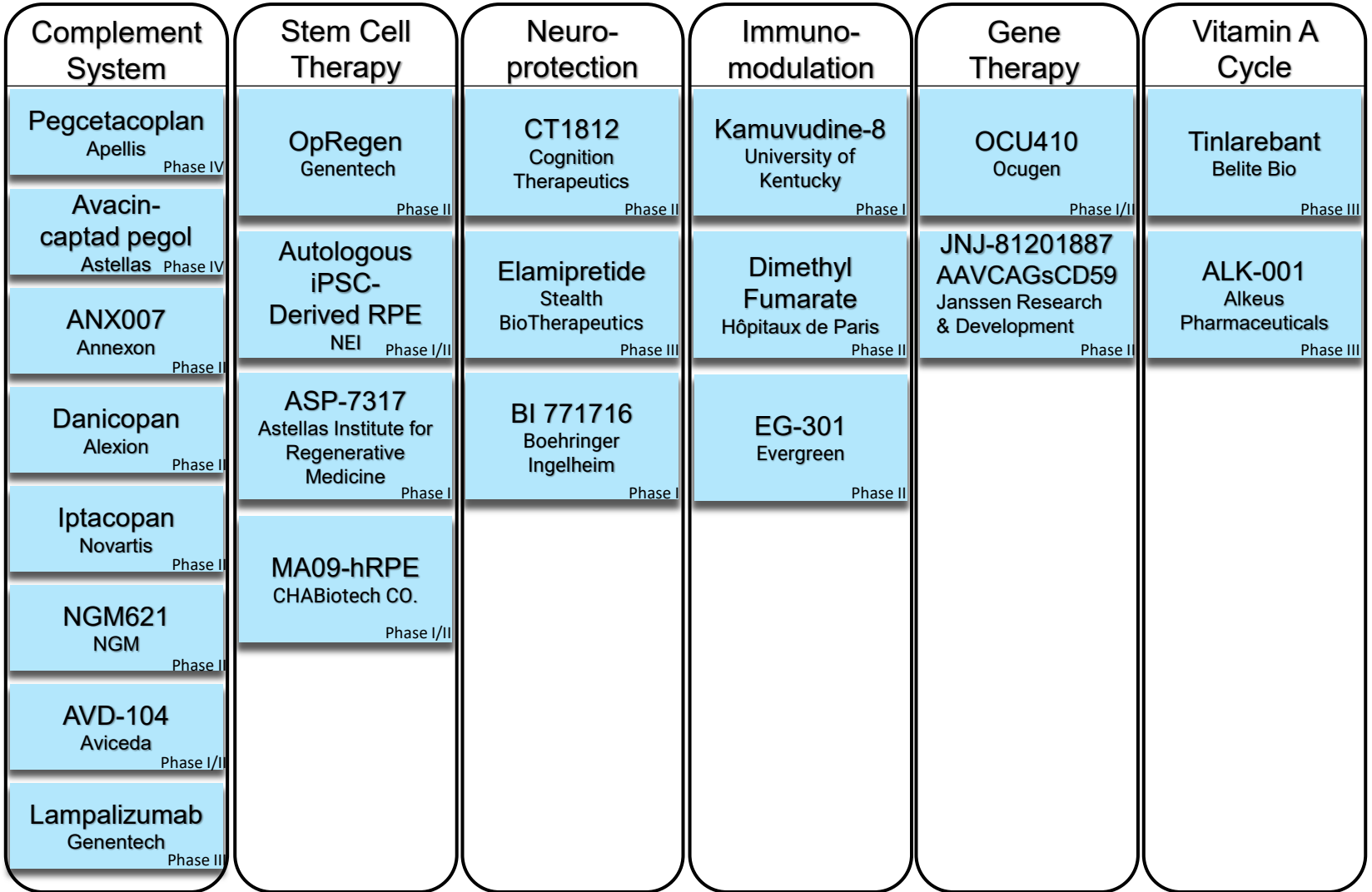
Grants: Acucela, Allergan, Apellis, Bayer, Bioeq, Centervue, Geuder, Roche/Genentech, Heidelberg Engineering, ivericBio, NightStarx, Novartis, Kanghong, Zeiss

Consulting: Acucela, Alcon, Alexion, Apellis, Bayer, Biogen, Boehringer-Ingelheim, Genentech/Roche, Grayburg Vision, Heidelberg Engineering, ivericBio, Lin Bioscience, Novartis, Oxurion, La Science, Stealth Biotherapeutics, Zeiss

Geographic Atrophy due to AMD

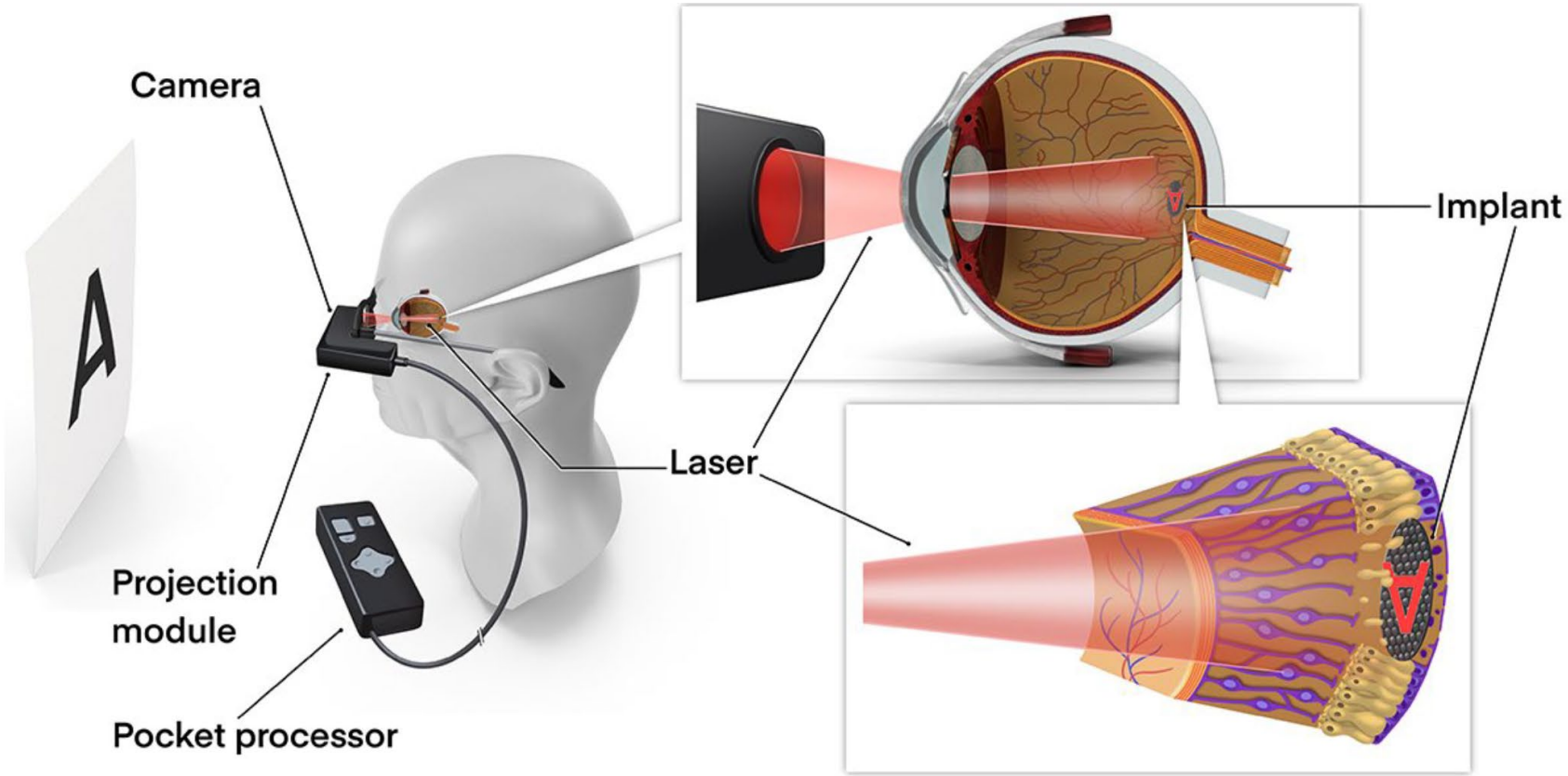





Complement System
Pegcetacoplan
Apellis
Phase IV
Avacin-captad pegol
Astellas
Phase IV
ANX007
Annexon
Phase II
Danicopan
Alexion
Phase II
Iptacopan
Novartis
Phase II
NGM621
NGM
Phase II
AVD-104
Aviceda
Phase I/II
Lampalizumab
Genentech
Phase II
Stem Cell Therapy
OpRegen
Genentech
Phase II
Autologous iPSC-Derived RPE
NEI
Phase I/II
ASP-7317
Astellas Institute for Regenerative Medicine
Phase I
MA09-hRPE
CHABiotech CO.
Phase I/II
Neuro-protection
CT1812
Cognition Therapeutics
Phase II
Elamipretide
Stealth BioTherapeutics
Phase III
BI 771716
Boehringer Ingelheim
Phase I
Immuno-modulation
Kamuvudine-8
University of Kentucky
Phase I
Dimethyl Fumarate
Hôpitaux de Paris
Phase II
EG-301
Evergreen
Phase II
Gene Therapy
OCU410
Ocugen
Phase I/II
JNJ-81201887
AAVCAGsCD59
Janssen Research & Development
Phase II
Vitamin A Cycle
Tinlarebant
Belite Bio
Phase III
ALK-001
Alkeus Pharmaceuticals
Phase III

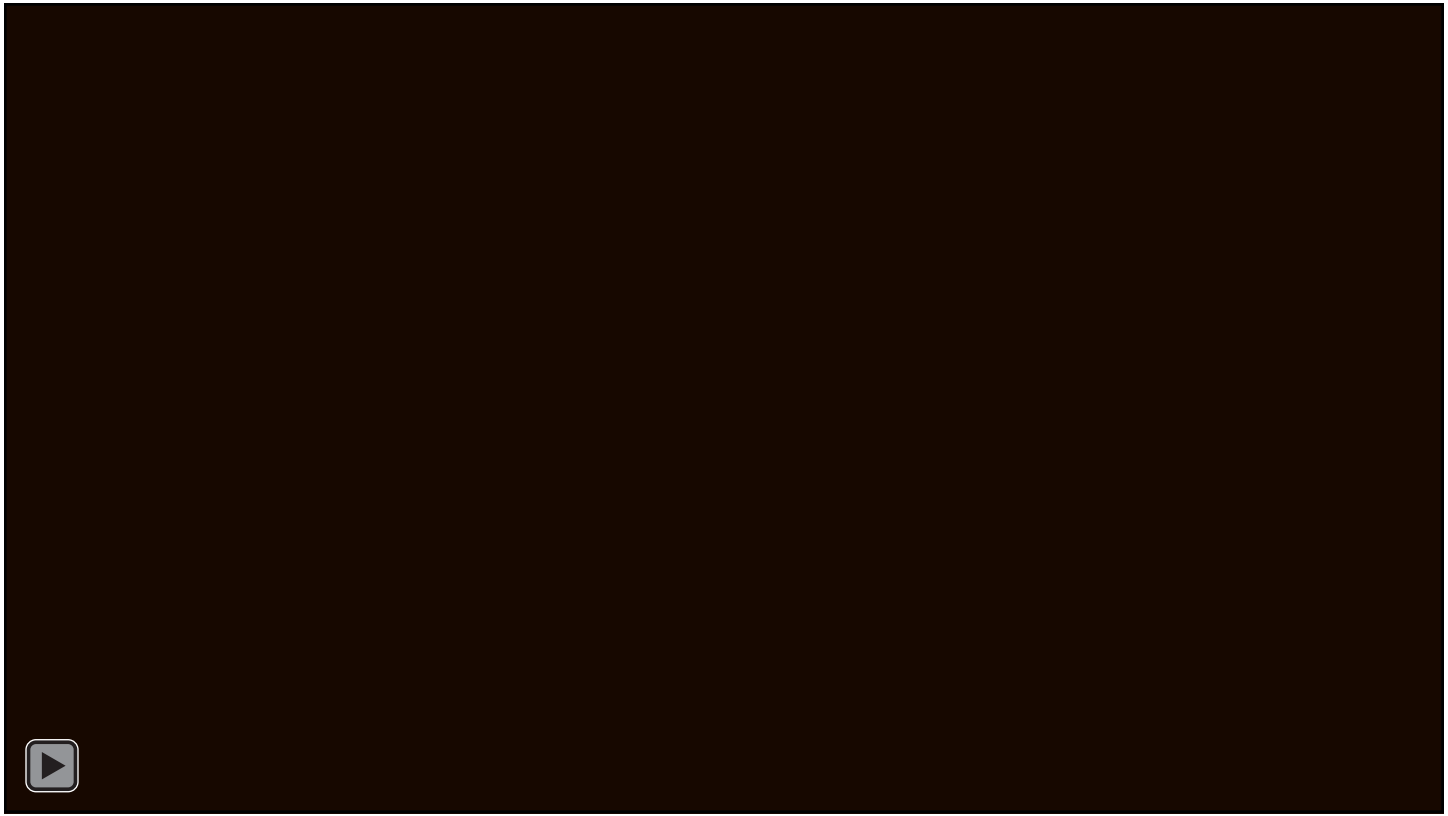
PRIMA Mechanism of Action

The PRIMA System was developed by Pixium Vision and has recently been acquired by Science Corporation

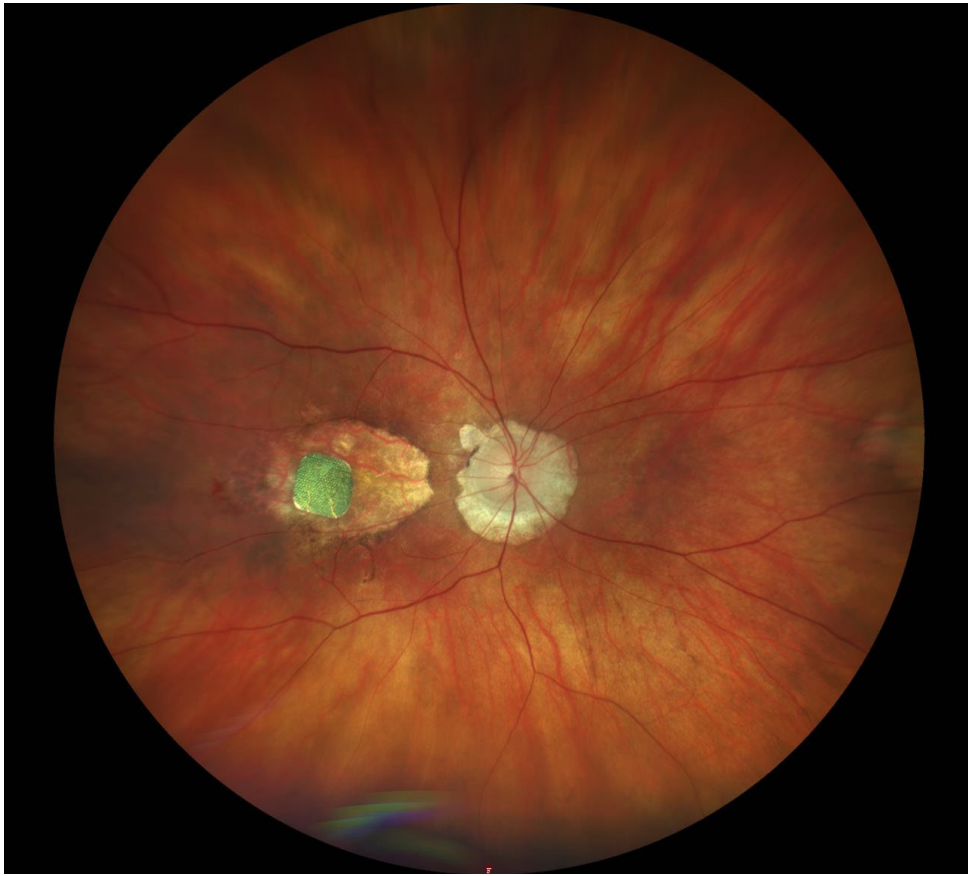


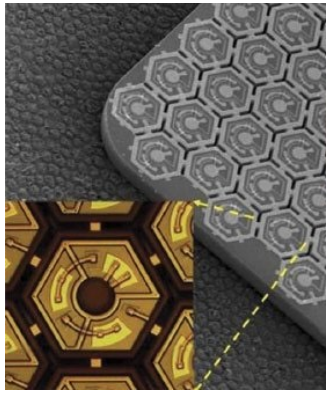
PRIMA is an investigational device and is not approved for sales

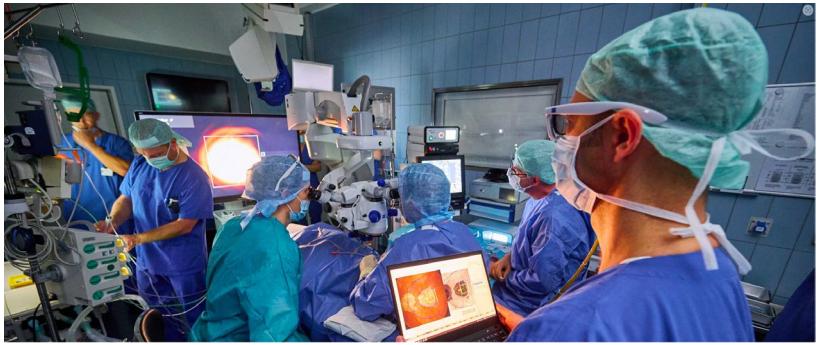
The PRIMA Retinal Implant System



PRIMA Implant - Wireless Microchip







PRIMA Clinical Trials

Purpose

To determine the visual acuity results of patients with geographic atrophy due to AMD following subretinal surgical implantation of the PRIMA neurostimulation system

FS Study France	FS Study US	PRIMAvera
Feasibility Study 5 Subjects GA logMAR ≥ 1.3 (20/400) First implant 2017 1 Site 72 month follow up Primary endpoint: visual perception	Feasibility Study 4 Subjects GA logMAR ≥ 1.3 (20/400) First implant 2020 36 months follow up 1 Site Primary endpoint: Landolt acuity	Pivotal Study 38 subjects GA logMAR ≥ 1.2 (20/320) First implant 2022 36 month follow up 17 sites Primary endpoint: Letter acuity

PRIMA Feasibility: ETDRS Results 4 years

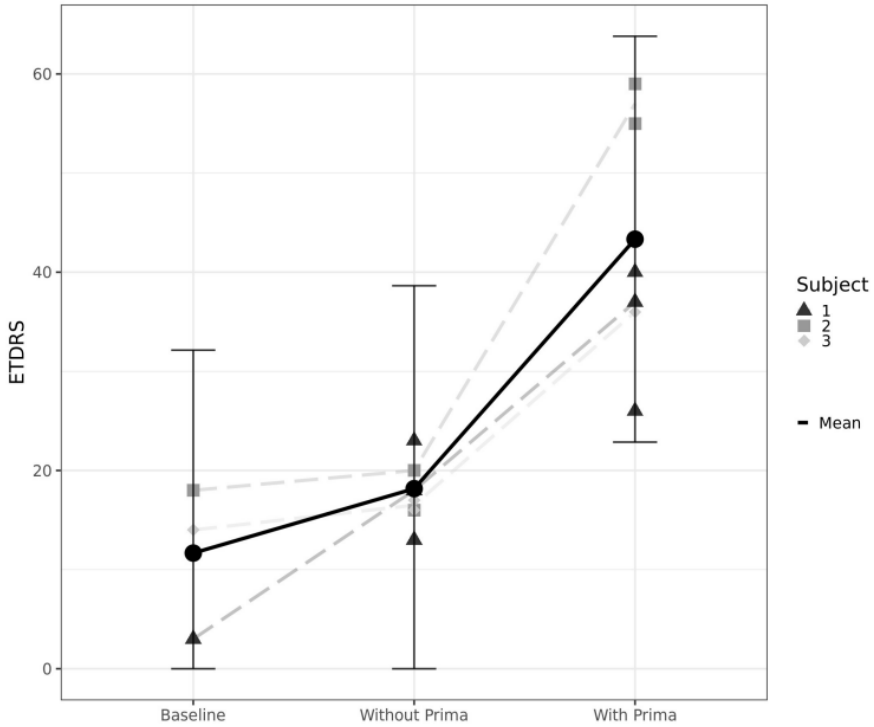


Figure 6: Median best-corrected prosthetic VA with the ETDRS chart at 1 meter distance.

+ 32 letters vs. baseline

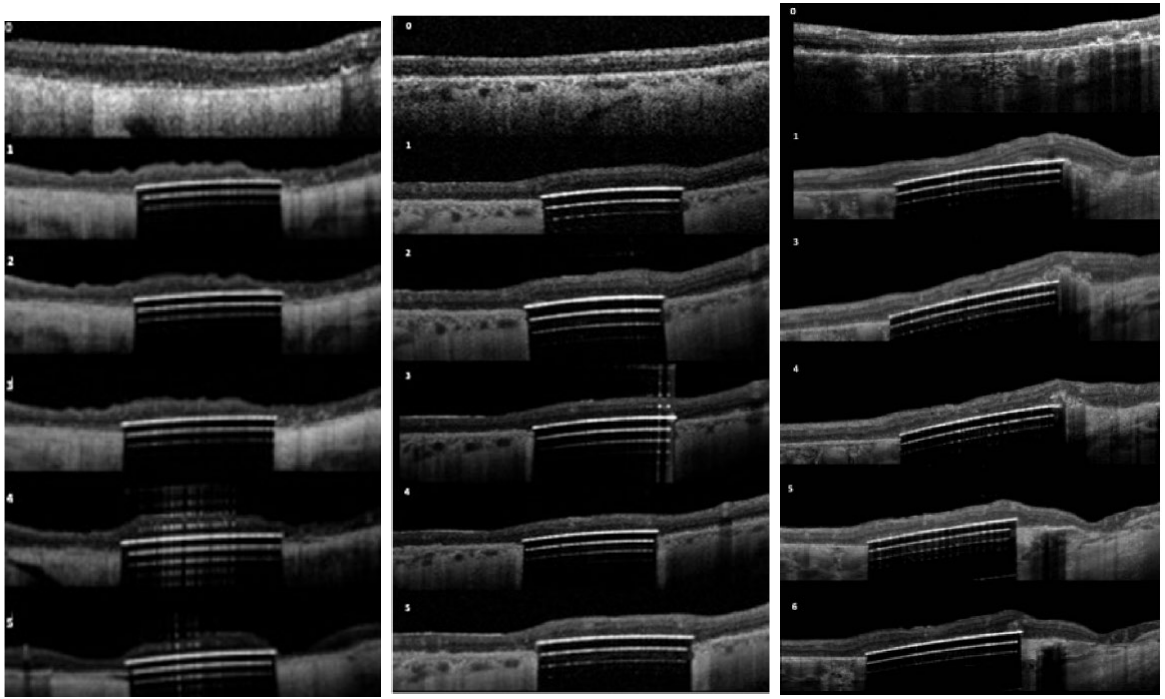
(ranging from 22 to 39 letters) versus baseline (SE 5.1) 95% CI [13.4,49.9]; p<0.0001.

Image processing includes magnification up to x8

Two subjects were excluded from the analysis:
1 subject-died unrelated to the study
1 subject- the implant was injected in the choroid

Muqit M., Le Mer Y., de Koo L.O., Holz F.G., Sahel J. & Palanker D., Prosthetic Visual Acuity with the PRIMA Subretinal Microchip in Patients with Atrophic Age-related Macular Degeneration at 4 years follow-up, **Ophthalmology Science (2024)**

Long-term Observations of Macular Thickness after Subretinal Implantation of a Photovoltaic Prosthesis in Patients with Grographic Atrophy - 3 years



Baseline

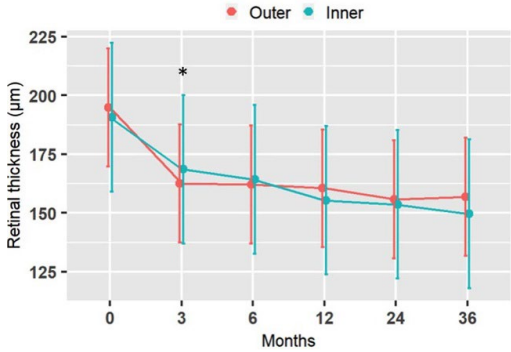
3 months

6 months

12 months

24 months

36 months

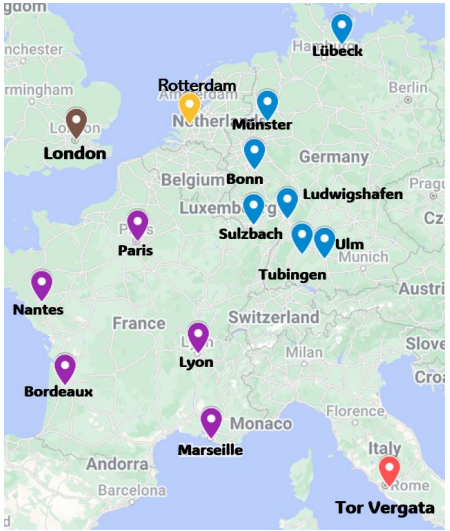


Muqit M, Le Mer Y, Holz FG, Sahel JA. J Neural Eng 2022

- Decrease in RT above the implant by 30 ± 12 µm during the first 3 months following surgery
- Macular layers then remained stable up to 36 months

PRIMAvera Pivotal Study Design

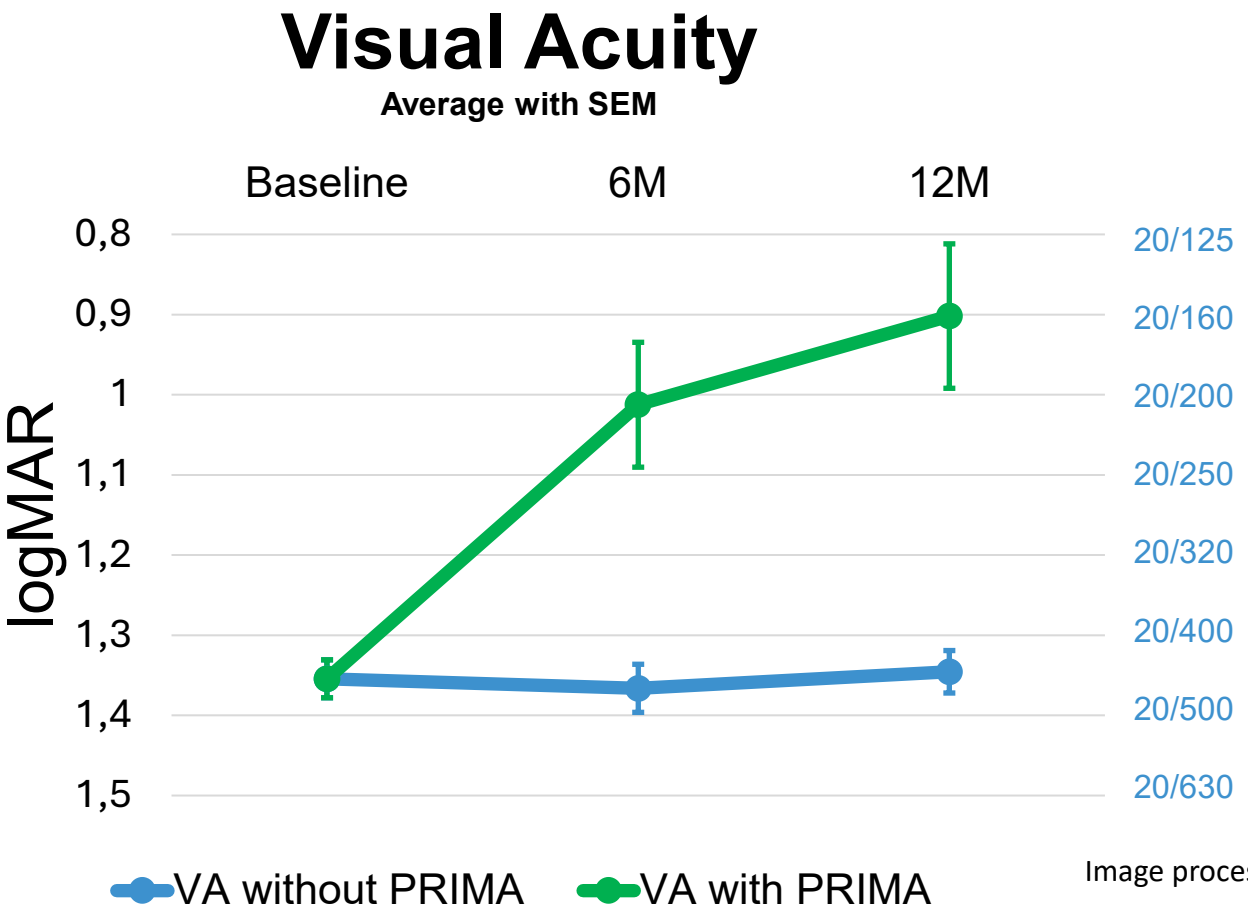
- Pivotal multicenter study in EU/UK (equivalent ot phase 3)
- Open label, non-randomized
- Study patients:
  - **38 patients** with GA, age 60 years or older
  - GA with foveal involvement with scotoma at least the implant size >4.5 mm^2
  - logMAR 1.2 (**20/320**) or worse
- Efficacy endpoints: Visual acuity (ETDRS), Quality of life (IVI), Central visual perception
- Follow up: **36 month with primary analysis after 12 months**
- **17 sites across 5 countries**



Demographics:

- Mean age: 78.9 years
- 20 female: 18 male
- Diagnoses: 9.5 years
- Mean atrophy size: 24.7mm^2

PRIMAvera preliminary results



Mean improvement: 23 letters
Best patient improved by 59 letters

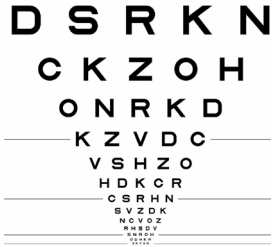
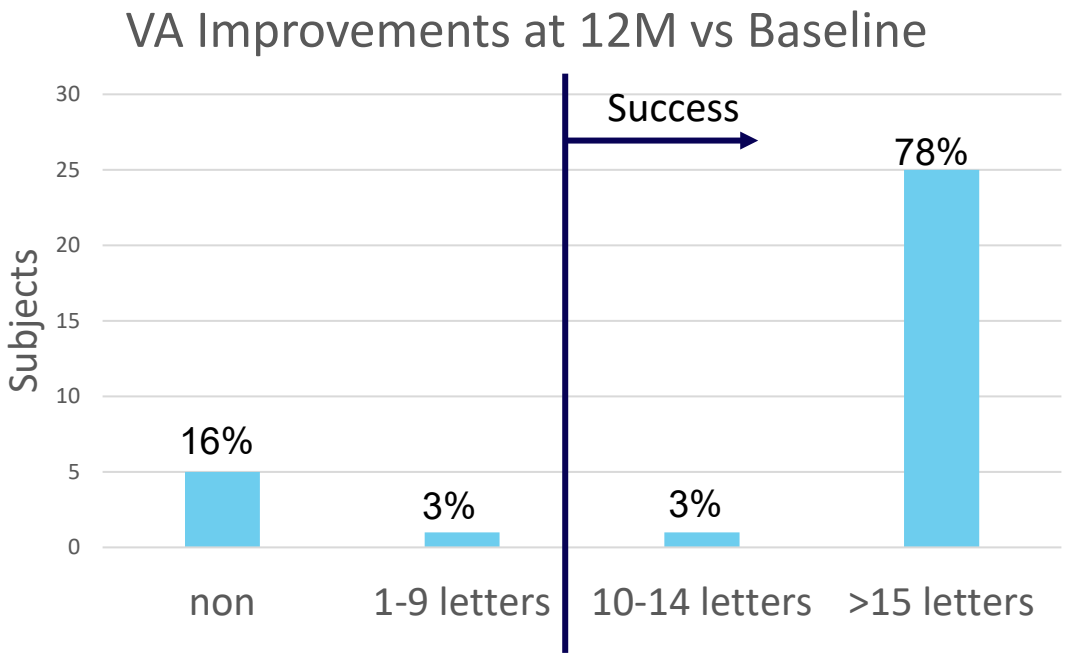


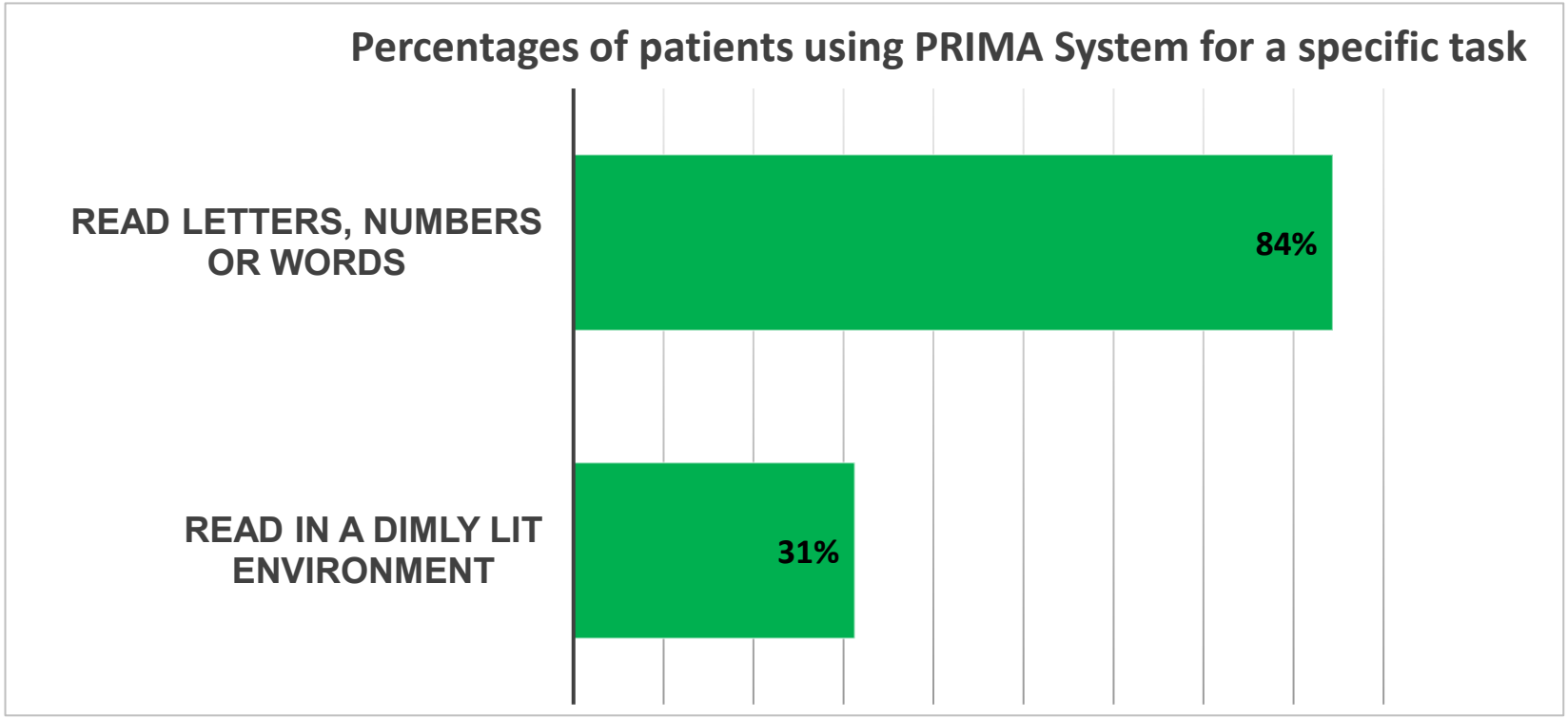
Image processing includes magnification up to x8

Primary endpoint



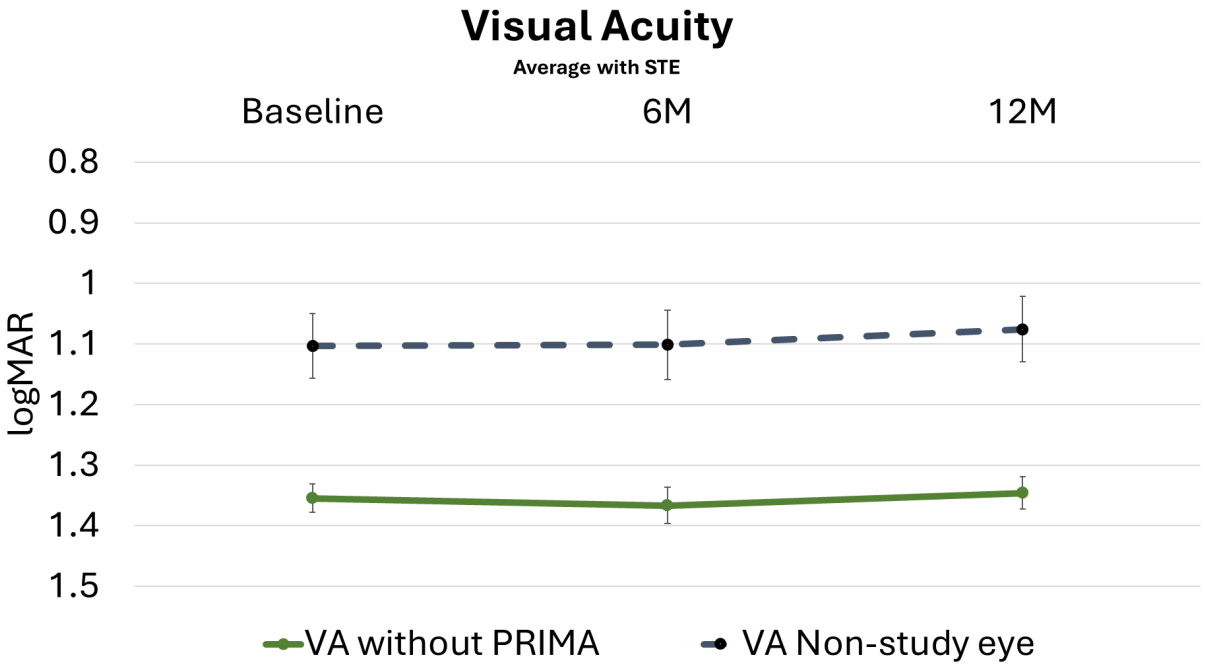
Preliminary data

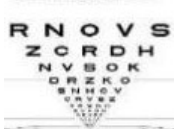
Main Home Use Applications



Preliminary data

Safety: Natural Visual Acuity (ETDRS) Pivotal study





PRIMA could be safely implanted under the atrophic macula while preserving the residual natural peripheral visual acuity, measured via ETDRS in the Feasibility study

Related Serious Adverse Events

SAE name	Number of cases/implanted subjects	Satus
Retinal break	8/38	7 resolved 1 ongoing
Hypertony in study eye	6/38	Resolved
Subretinal hemorrhage	6/38	Resolved
Retinal hemorrhage	1/38	Resolved
Asymptomatic choroidal neovascularization (CNV)	2/38	Resolved
Thrombophlebitis of right thigh and lower leg	1/38	Resolved
Choroidal fold	1/38	Resolved
Retinal detachment	1/38	Resolved
Proliferative vitreoretinopathy (PVR)	1/38	Ongoing

CONCLUSIONS

- PRIMA can restore meaningful visual acuity in patients with foveal involving GA, where photoreceptors are already lost
- Patients can use the device for reading letters, numbers, and words, some patients can even read longer text
- Integration of natural peripheral and artificial vision is possible
- While other therapies for GA aim at slowing progression, the PRIMA system may improve functional outcomes by restoring central vision

Clinical Partners for EU Studies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Bonn, DE


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Ludwigshafen, DE


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Münster, DE


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