

**modulight**

# Lasers in Ophthalmic Applications

## EPIC Online Technology Meeting on Ophthalmology



*Petteri Uusimaa, VP & CTO*  
*29<sup>th</sup> June 2020*

*Lasers and optics for personalized  
medicine and better life.*

## Modulight, Inc.

- ❑ The only vertically integrated medical laser manufacturer in the world
- ❑ Profitable privately held company with 20 years track record
- ❑ Exclusive supplier to 10+ pharmas & world leading cancer centers in USA & Europe
- ❑ Long track record of making all kinds of semiconductor lasers & pumps (400–2000 nm)
- ❑ Certified ISO13485 QMS in 2011, ISO9001 & 14001 in 2002
- ❑ Co-branded & OEM products currently shipping to all continents except Antarctica





## Life sciences

- ❑ Medical laser systems
- ❑ Oncology
- ❑ Ophthalmology

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- ❑ Optogenetics
- ❑ Pharmaceutical safety & testing



## Custom & industrial

- ❑ Subsystems for challenging optics & electronics
- ❑ Processing



## Services

- ❑ Regulatory & engineering
- ❑ Lifecycle support





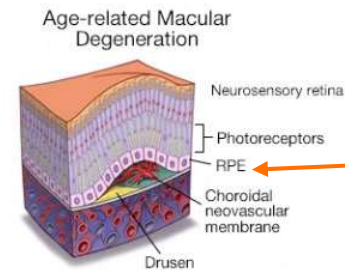
### **Topics today**

- AMD, CNV and other retinal diseases*
- Lasers and PDT for ophthalmic application*
- Modulight ophthalmic laser platforms*
- Summary*

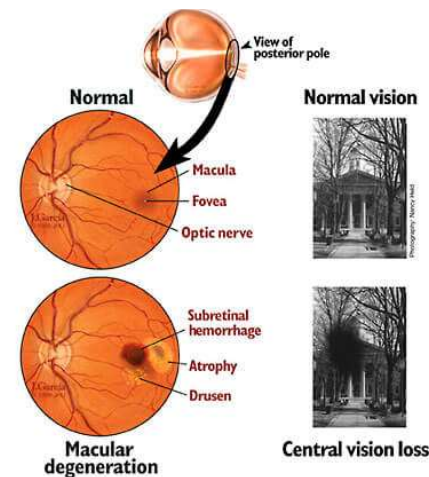
# Introduction to AMD

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- ❑ AMD is neurodegenerative disease
  - ❑ Characterized by development of CNV and consequent irreversible damage in the macula
- ❑ AMD usually starts slowly and asymptotically (dry form)
  - ❑ More than 8 million people have earlier stages of AMD
  - ❑ In c. 10% of cases, dry AMD progresses to wet (neovascular/exudative) AMD
- ❑ Late AMD is divided into geographic atrophy and neovascular AMD (nAMD)
  - ❑ nAMD represent about 55% of all late AMD cases and is leading overall cause of blindness in people over 65, causing 90% of AMD-related blindness

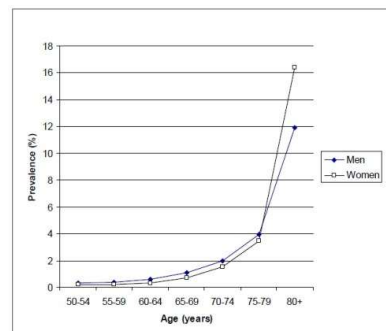


Drusen (dry AMD) or choroidal neovessels (wet AMD) build up beneath RPE

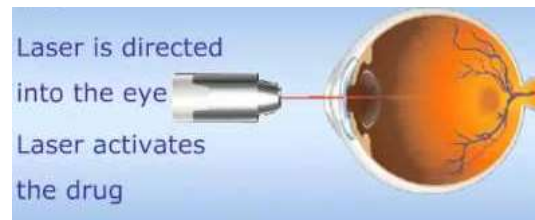
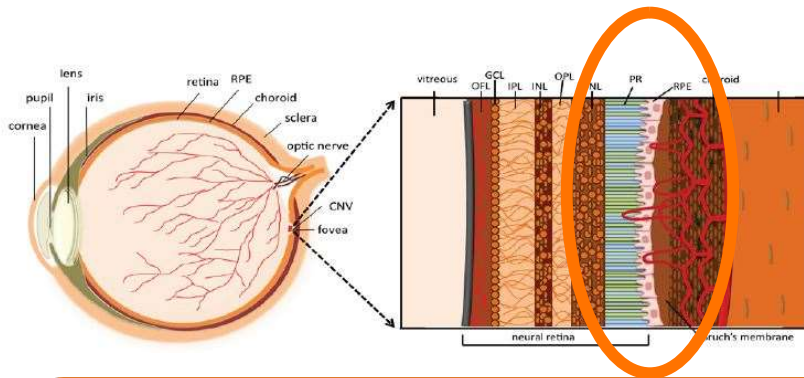


Central vision loss

- ❑ Prevalence in USA is anticipated to increase from **11 million (2016) to 22 million by the year 2050**
- ❑ Global prevalence increment from **170 million (2016) to 288 million by the year 2040**
- ❑ High prevalence leads to an **annual \$4.6 billion direct healthcare costs in the US**, and anticipated to increase



# Introduction to CNV



## Benefits of PDT

- ❑ Slow the progression of nAMD and even stabilize visual acuity for many years
- ❑ Damage to the overlying retina is minimized (less destructive), functional vision is maintained, excellent cosmetic effects & relatively few side effects
- ❑ Minimally invasive, outpatient setting: IV injection vs. intravitreal anti-VEGF injections), laser is non-thermal
- ❑ Low mutagenic potential
- ❑ Can reduce exudation that is resistant to anti-VEGF monotherapy

- ❑ Choroidal neovascularization (CNV): angiogenesis leads to vascular sprouting from the choroid into Bruch's membrane, sometimes capable of even perforating RPE
- ❑ CNV can result from many primary disorders [3]
  - ❑ **Neovascular AMD (most common)**
  - ❑ Pathological myopia
  - ❑ Presumed ocular histoplasmosis
  - ❑ Angioid streaks
  - ❑ Polypoidal choroidal vasculopathy (PCV)
  - ❑ Central Serous Retinopathy (CSR)
  - ❑ Choroidal hemangiomas

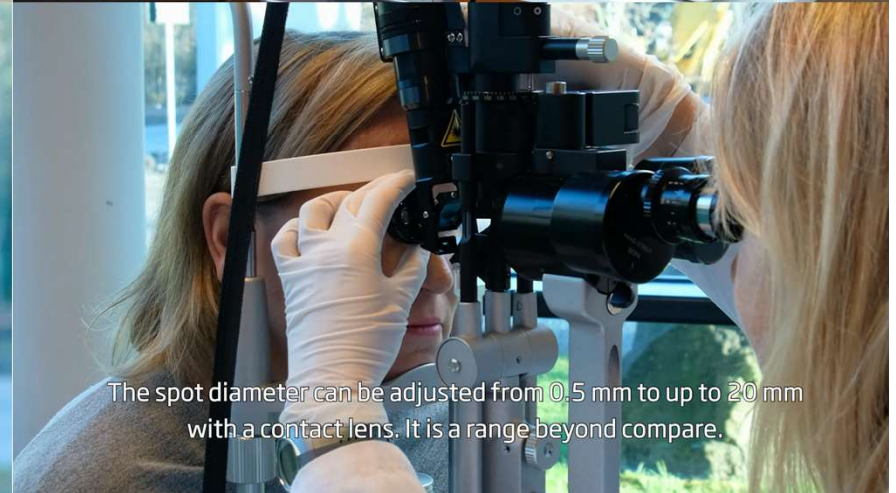
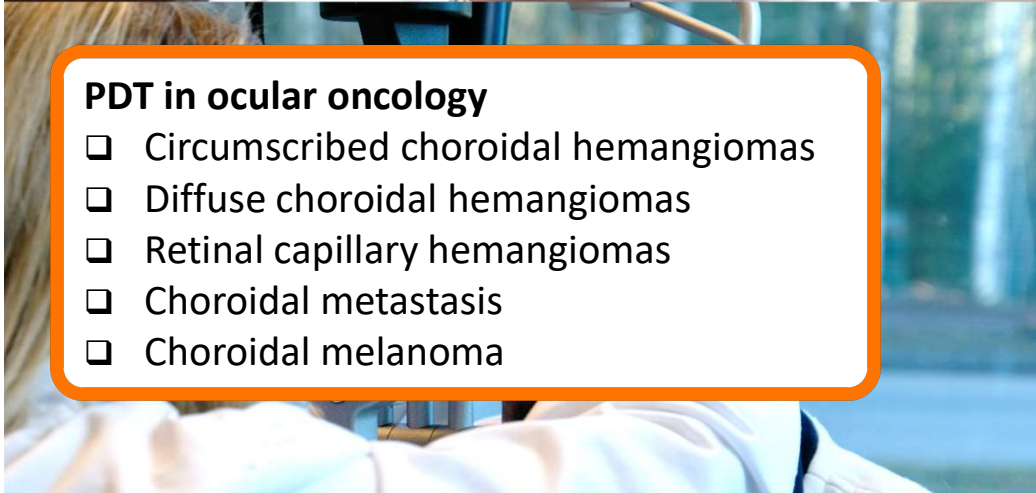
PDT approved

Not on label yet

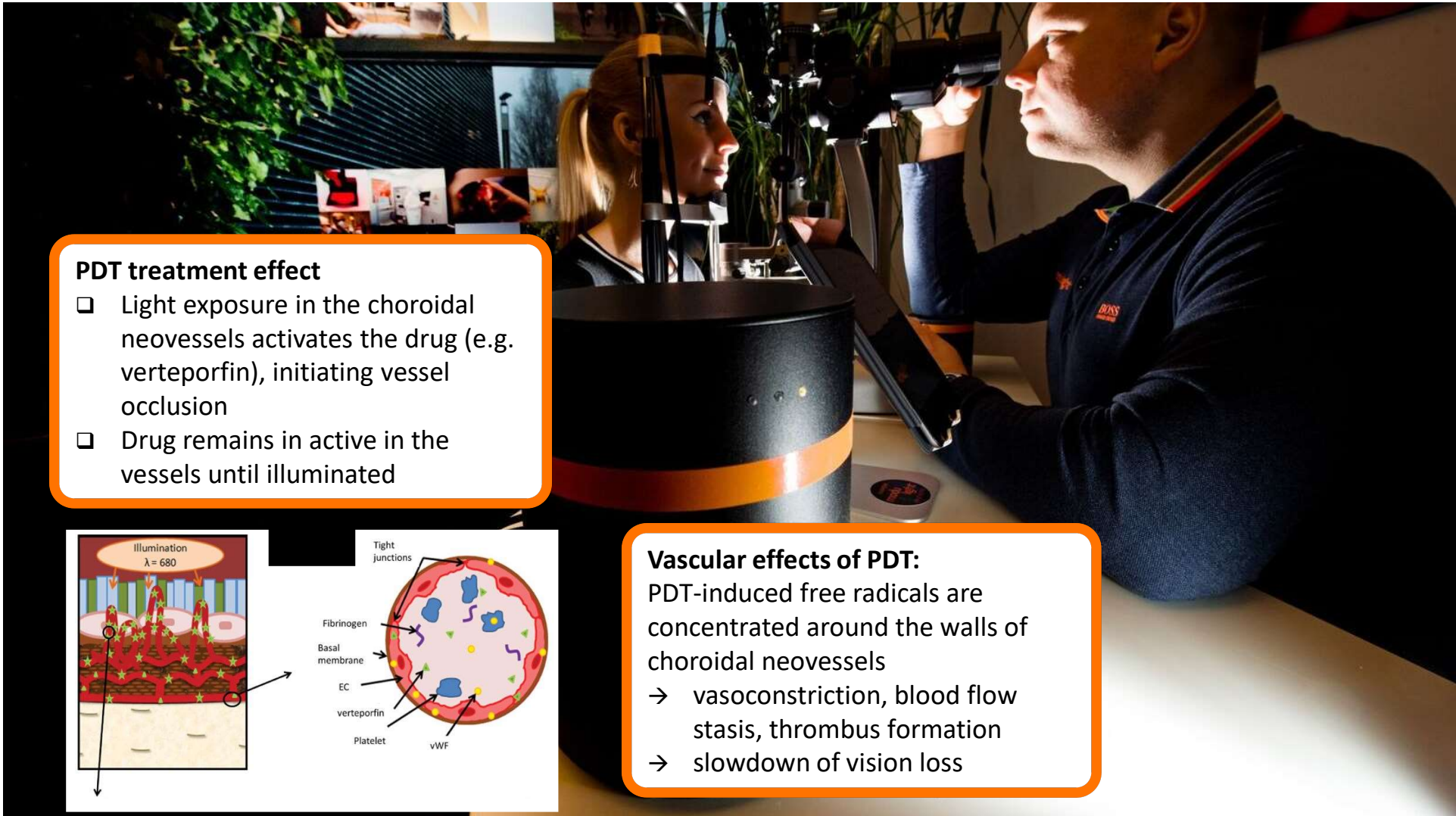


### PDT in ocular oncology

- Circumscribed choroidal hemangiomas
- Diffuse choroidal hemangiomas
- Retinal capillary hemangiomas
- Choroidal metastasis
- Choroidal melanoma

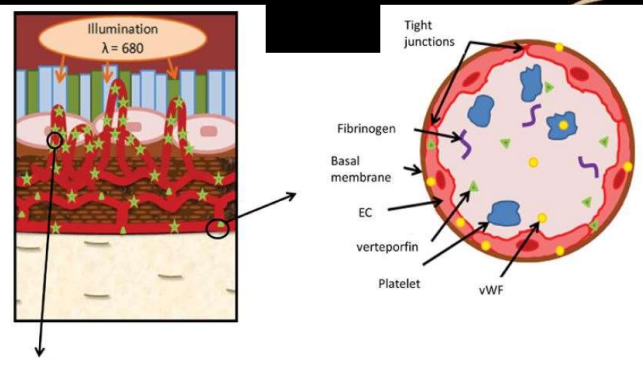


The spot diameter can be adjusted from 0.5 mm to up to 20 mm with a contact lens. It is a range beyond compare.



### PDT treatment effect

- ❑ Light exposure in the choroidal neovessels activates the drug (e.g. verteporfin), initiating vessel occlusion
- ❑ Drug remains in active in the vessels until illuminated



### Vascular effects of PDT:

- PDT-induced free radicals are concentrated around the walls of choroidal neovessels
- vasoconstriction, blood flow stasis, thrombus formation
  - slowdown of vision loss



Laser device for ophthalmology – ML6710i



**ML6710i is a medical laser device for ophthalmology.** ML6710i is designed for treatments in various ophthalmic indications. The laser is controlled intuitively from **iPad app** – the wireless connection allows flexibility for the treatment setup. A must-have tool for anyone in the field of ophthalmology. The laser beam is formed into a circular, adjustable and highly uniform spot by Modulight's laser beam shaper.

**Designed for ophthalmologists**

Every part and feature within ML6710i is designed to fulfill one goal: enabling **safe and efficient ophthalmic treatments** for patients and doctors. Read here why **Bausch + Lomb chose Modulight** as their exclusive laser provider! The laser itself is packaged in an elegant and durable metallic case. The laser device is accompanied by an iPad mini, which is used for setting up the treatment and controlling the laser. The user interface has been optimized for easiness of use, while keeping up with the strict requirements of a medical laser. ML6710i is connected to **Modulight cloud**, which enables safe storing of treatment logs, while not exposing patient data. The laser light is formed into a **uniform circular spot by Modulight laser beam shaper**. The beam shaper can be attached into all common slit lamps. ML6710i has the standard wavelength of 689 nm but according to customer wishes it can be built to include a different wavelength. When ordering, you may request a wavelength from the range 400-2000 nm – just ask **Modulight sales team**. The laser light output comes conveniently from a receptacle fiber with a standard SMA-905 connector. *\* the product is not FDA approved \**

The most advanced laser in ophthalmology, ML6710i

**Key features**

- The default bulb-in laser is 689 nm, 400 mW output power
- Aiming beam (laser class 2) 635 nm
- Possible to select any other Modulight laser in the wavelength range of 400-2000 nm and power up to 3 W
- Laser beam shaper easily attached to all common slit lamps
- Treatment spot diameter adjustable to up to 14 mm diameter with 500 micrometers
- Laser on/pause controlled by a foot switch
- Key switch and interlock for laser safety

**Benefits**

ML6710i is a modern ophthalmic laser which is very easy an intuitive to operate. Thanks to the Modulight Cloud, all the operating parameters and laser on/off/pause events are safely stored into treatment log. Setting the treatment parameters is very easy, thanks to the iPad app. Laser on/pause can be controlled by a foot switch.

**Applications in ophthalmology**

- ophthalmic photodynamic therapy
- age-related macular degeneration
- uveal melanoma
- ocular melanoma



**Technical specifications**

Wavelength	Laser output power	Aiming beam	Treatment spot size	Irradiance
689 nm	400 mW class 3B	635 nm class 2	up to 14 mm	600 mW/cm <sup>2</sup>

**Links related to ophthalmology & ML6710i laser system**

[ML6710i datasheet \(preliminary\)](#) | [Modulight medical laser range](#) | [Press Release: Modulight exclusive laser supplier for B+L](#)



**Modulight laser platforms for AMD and other ophthalmic treatments**

- ❑ Single channel and multi-channel solutions (ML6710i & ML7710)
- ❑ Combination therapy (PDT) or laser direct treatment
- ❑ Light delivered by Modulight beam shaper with superior performance
- ❑ Full treatment solution with slit lamp adapter & eye microscope








# Regulatory approaches and quality management services

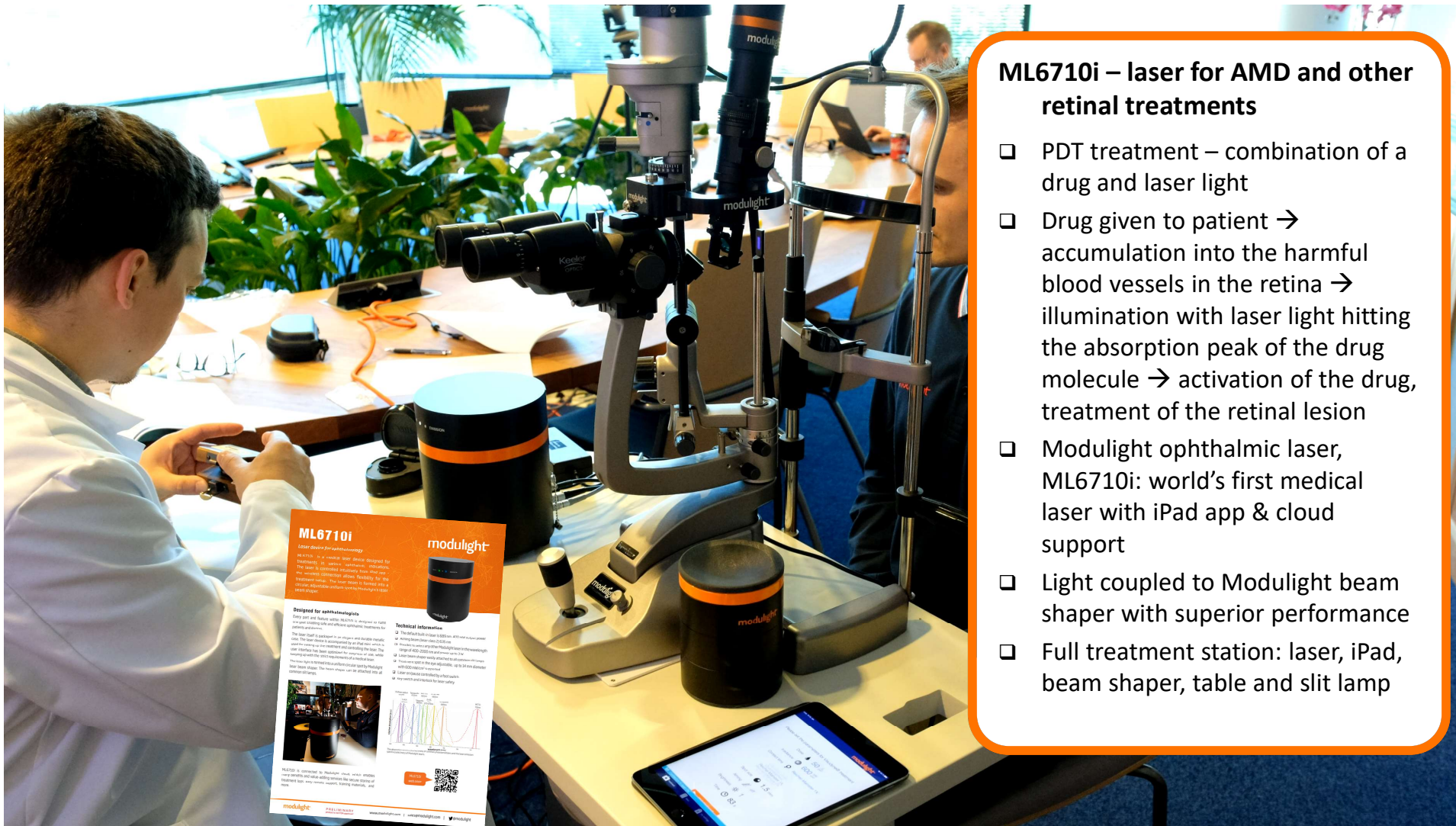


## EUROPE



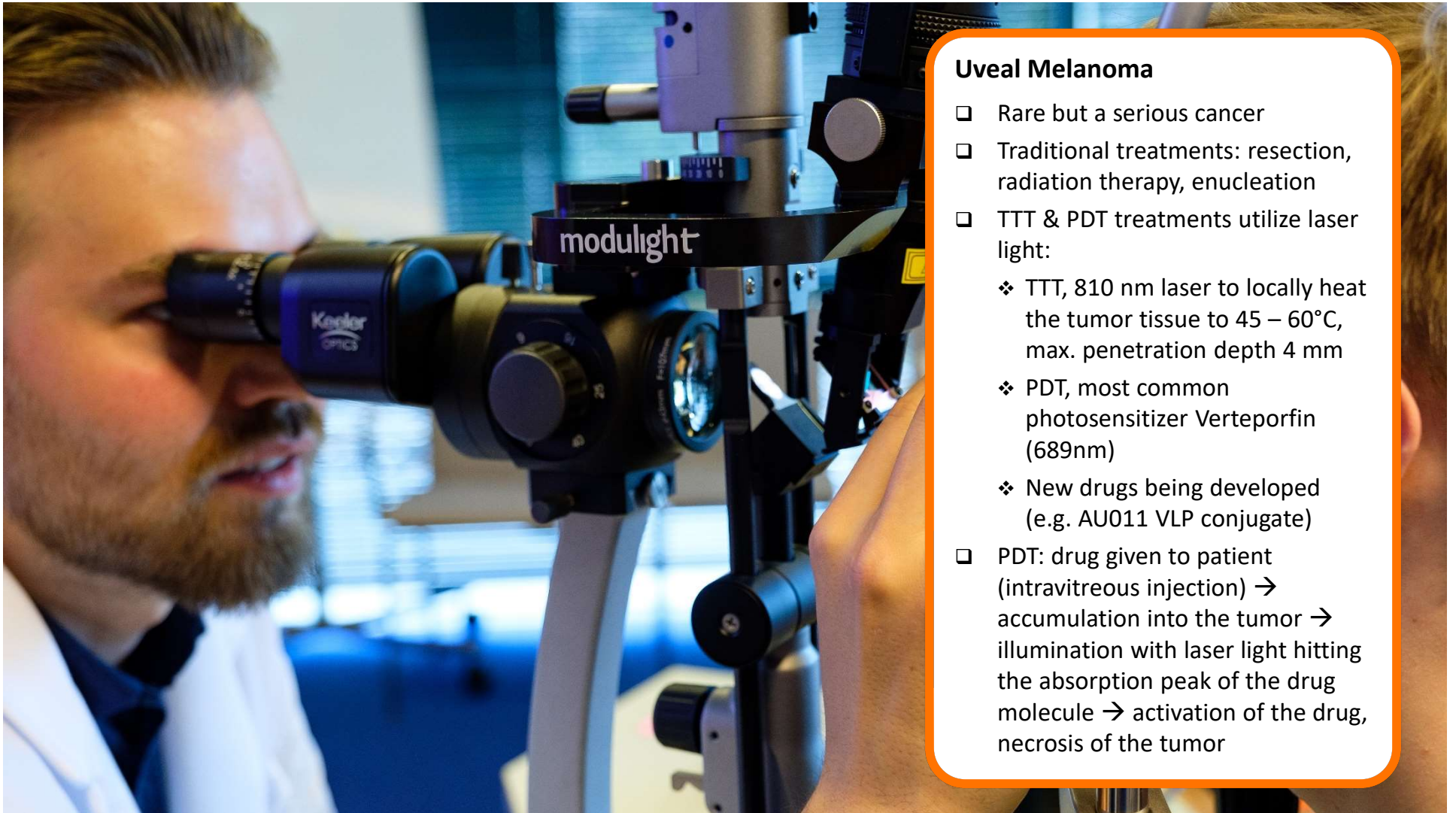
## USA

REGULATORY SERVICE	MODULIGHT CE MARK Modulight creates technical file and applies for CE mark on behalf of customer	PRIVATE LABEL CE MARK Modulight provides technical content for CE mark submission	IND / IDE Modulight assists with regulatory submission	510 (k) FDA approved device	PMA Modulight has solid experience delivering full FDA PMA regulatory submission file
PROCESS	<p><b>Product tested</b> towards CB certification <span style="float: right;">3</span></p> <p><b>Modulight manages CE application process</b> and initial factory audit <span style="float: right;">2</span></p> <p><b>Subsequent factory audits</b> and unannounced inspections <span style="float: right;">1</span></p> <p><b>Modulight can ship products</b> directly to end user</p> <p>Modulight manages medical device reporting and post-market surveillance <span style="float: right;">2</span></p> <p><b>Registration with local health authorities</b> (Clinical evaluation provided by customer)</p>	<p><b>Product tested</b> towards CB certification <span style="float: right;">3</span></p> <p><b>Product manufactured</b> according to customer specification under Modulight ISO 13485 certified quality system</p> <ul style="list-style-type: none"> <li>❑ Customer required to have certifications for QMS, including post-market surveillance and medical device reporting and registration with local health authorities, customer responsible for managing factory audits and unannounced inspections, and CE marking submission including clinical evaluation</li> <li>❑ Agreement with Modulight for allowing customer NB to audit Modulight as critical subcontractor</li> <li>❑ Customer needs to have physical presence in Europe</li> </ul>	<p><b>Modulight provides limited technical file</b> as deliverable to customer <span style="float: right;">3</span></p> <p><b>Product tested</b> towards CB certification <span style="float: right;">2</span></p> <p><b>Modulight applies for NRTL ATM</b>, manages IFA and subsequent quarterly audits by the NRTL representative <span style="float: right;">1</span></p> <ul style="list-style-type: none"> <li>❑ Customer registers for IND / IDE, required to report to FDA</li> </ul>	<p><b>Modulight provides technical file as device master file (MAF)</b> to FDA, customer refers to MAF in their application <span style="float: right;">3</span></p> <p><b>OR</b></p> <p><b>Modulight provides technical file as deliverable to customer</b> <span style="float: right;">2</span></p> <p><b>Product tested</b> towards CB certification <span style="float: right;">1</span></p> <p><b>CDRH submission</b> and yearly reports by Modulight (or customer) <span style="float: right;">2</span></p> <p><b>Modulight applies for NRTL ATM</b>, manages IFA and subsequent quarterly audits by the NRTL representative</p> <p><b>Modulight (and/or customer) registered as manufacturer for the product at FDA</b></p>	<p><b>Modulight provides technical file as device master file (MAF)</b> to FDA, customer refers to MAF in their application <span style="float: right;">3</span></p> <p><b>Modulight applies for NRTL ATM</b>, manages IFA and subsequent quarterly audits by the NRTL representative <span style="float: right;">2</span></p> <p><b>Modulight registered as manufacturer for the product at FDA</b></p> <ul style="list-style-type: none"> <li>❑ Modulight registered as manufacturer for the product at FDA</li> <li>❑ Agreement with Modulight to provide access to FDA for on-site inspection</li> <li>❑ CDRH submission and yearly reporting by customer (Modulight provides technical content)</li> </ul>
QUALITY MANAGEMENT	ISO 13485 certified 93/42/EEC and 2007/47/EC requirements	ISO 13485 certified	USFDA QSR requirements 21 CFR 820 and 21 CFR 1040 requirements	USFDA QSR requirements 21 CFR 820 and 21 CFR 1040 requirements	USFDA QSR requirements 21 CFR 820 and 21 CFR 1040 requirements
DURATION	8 months	10+ months	10 months	x months	16 months + xxx days
CASE EXAMPLES	 <p><b>MODULIGHT ML7710</b></p>		  		<p>Major US pharmaceutical company</p>



## ML6710i – laser for AMD and other retinal treatments

- ❑ PDT treatment – combination of a drug and laser light
- ❑ Drug given to patient → accumulation into the harmful blood vessels in the retina → illumination with laser light hitting the absorption peak of the drug molecule → activation of the drug, treatment of the retinal lesion
- ❑ ModuLight ophthalmic laser, ML6710i: world's first medical laser with iPad app & cloud support
- ❑ Light coupled to ModuLight beam shaper with superior performance
- ❑ Full treatment station: laser, iPad, beam shaper, table and slit lamp



### Uveal Melanoma

- ❑ Rare but a serious cancer
- ❑ Traditional treatments: resection, radiation therapy, enucleation
- ❑ TTT & PDT treatments utilize laser light:
  - ❖ TTT, 810 nm laser to locally heat the tumor tissue to 45 – 60°C, max. penetration depth 4 mm
  - ❖ PDT, most common photosensitizer Verteporfin (689nm)
  - ❖ New drugs being developed (e.g. AU011 VLP conjugate)
- ❑ PDT: drug given to patient (intravitreal injection) → accumulation into the tumor → illumination with laser light hitting the absorption peak of the drug molecule → activation of the drug, necrosis of the tumor

## Summary

### What we can do for you?

- ❑ Deliver a certified full treatment solution to ophthalmic applications
- ❑ Design & manufacture you a tailored medical laser system with life-cycle support
- ❑ Ensure long-term supply of critical product and parts including lasers&optics from own factory
- ❑ Be your partner in medical laser field

### What you can do for us?

- ❑ Be our partner for delivering highly controlled parts for medical devices
- ❑ Combine your biomedical process or technology knowhow as part of our product, e.g. imaging, sensors, theranostics



# Thank you!

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