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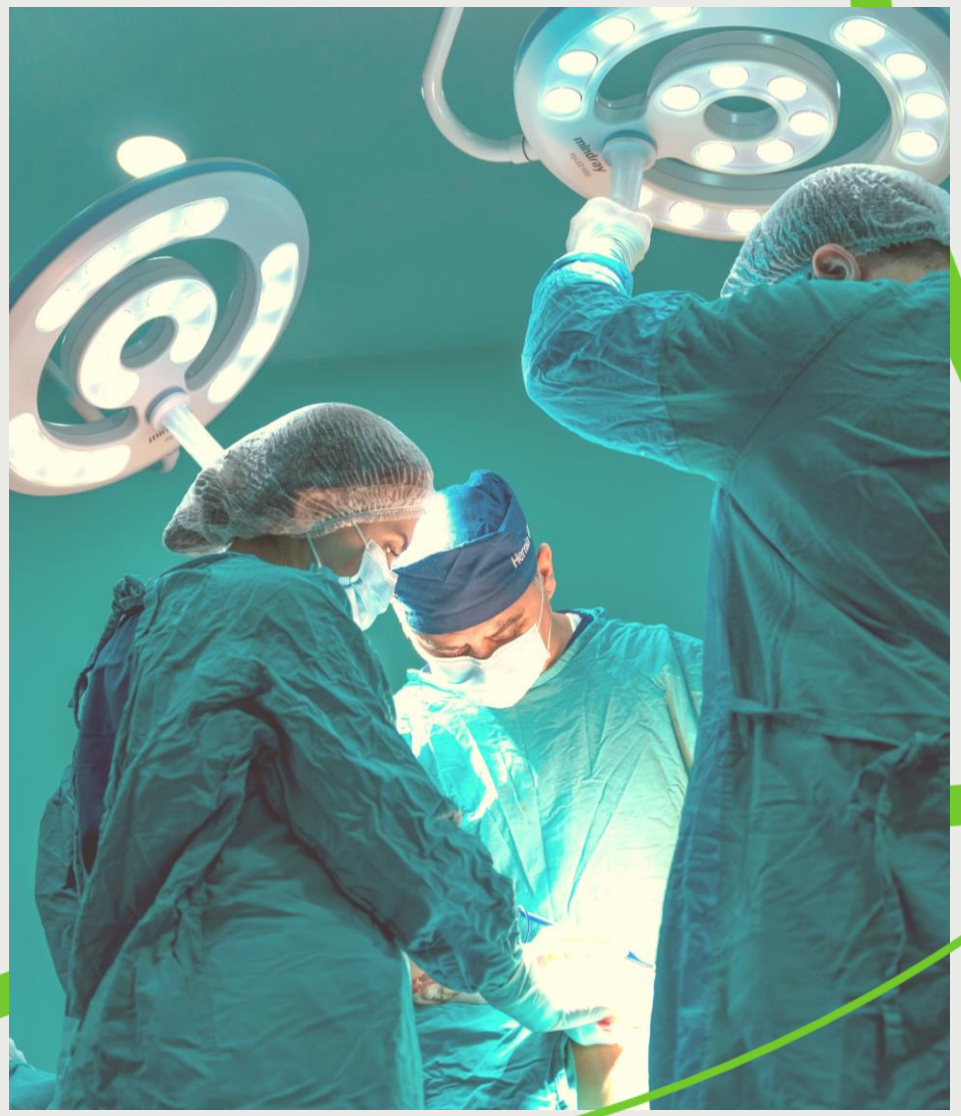
Precision surgery improving outcome for cancer patients



January 2024

Disclaimer

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Investment highlights

1 Publicly listed with dense news flow

- **Ticker:** FLUO (Nasdaq First North Stockholm)
- **Market cap:** ≈75 MEUR
- **Location:** Copenhagen, Denmark
- **Major investors** include Arbejdernes Landsbank and Linc AB

2 Unique uPAR-targeting technology platform

- Lead product FG001 **guides cancer surgery**
- **Positive phase II results** in aggressive brain cancer
- **Clinical proof of concept** in head & neck and lung cancers
- FG001 has **blockbuster** potential

3 Cancer recurs locally after surgery in 1:2 patients

- Cancer remains a huge health problem
- 80% of patients with cancer undergo surgery

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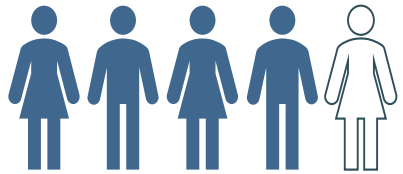
Cancer surgery today

Cancer remains to be one of the leading causes of death globally

18.1 million new patients

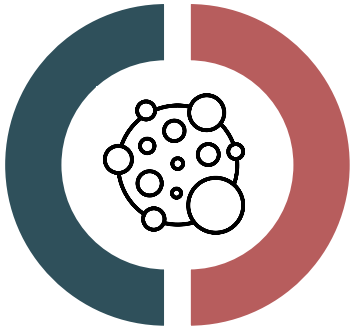
are diagnosed with cancer every year

Surgery is a primary treatment option for patients with localized cancer

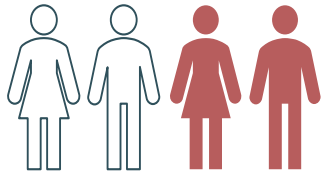


80% of patients undergo surgery

Local recurrence of cancer following surgery in



50% of patients



Best practice removing tumors relies largely on **visual localization** and **palpation**

Source: Cancer worldwide market research report by Marketline, worldwide in 2020

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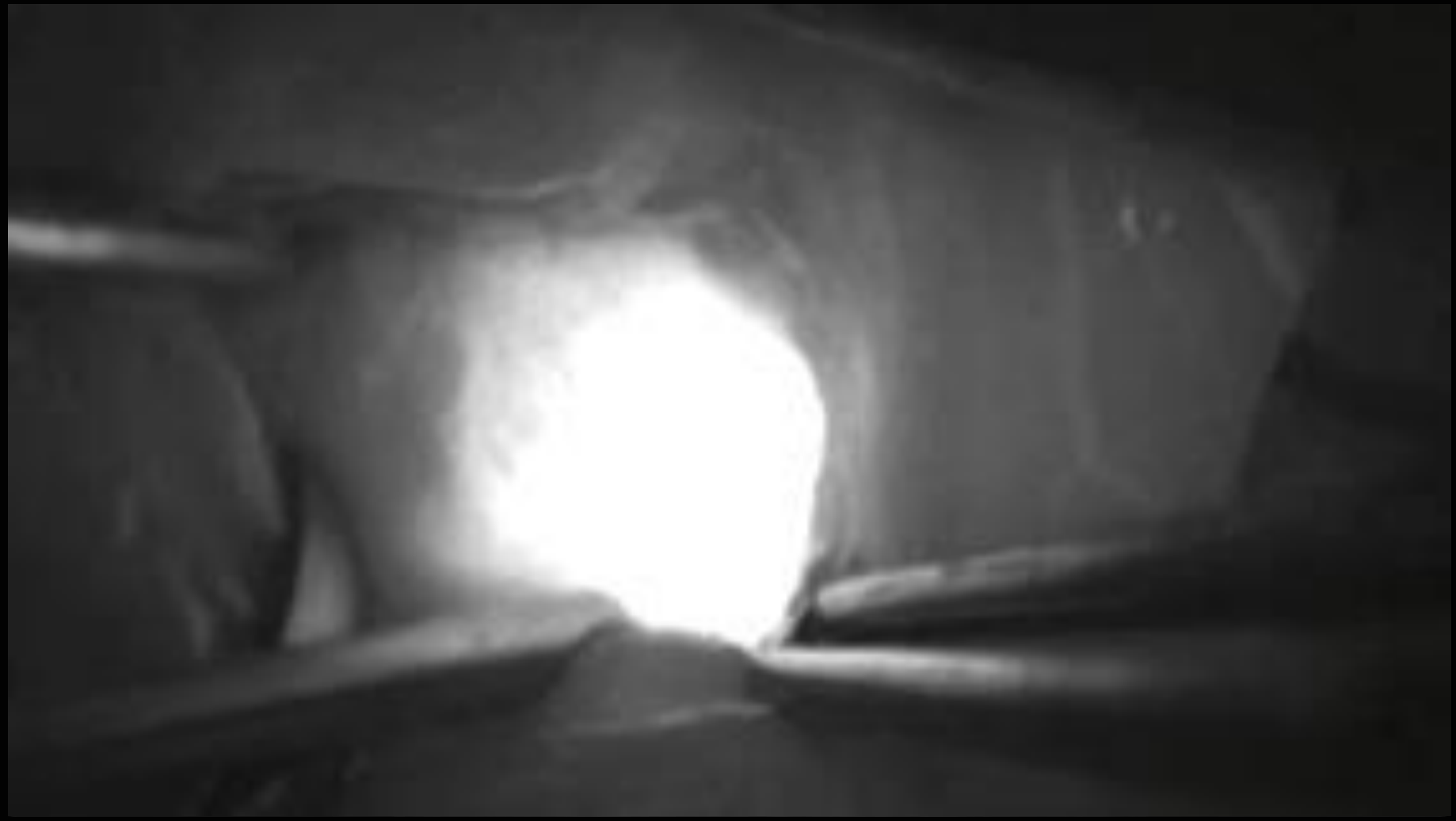
FluoGuide illuminates cancer

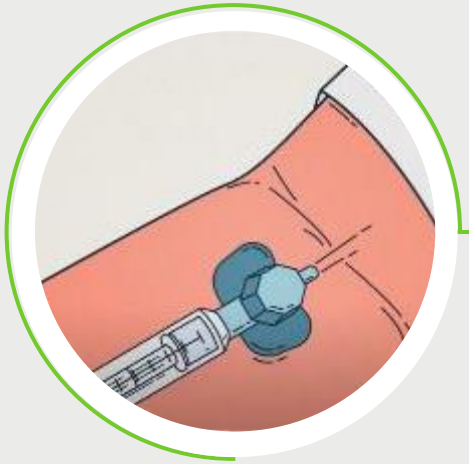


Source: FG001-CT-001, data on file

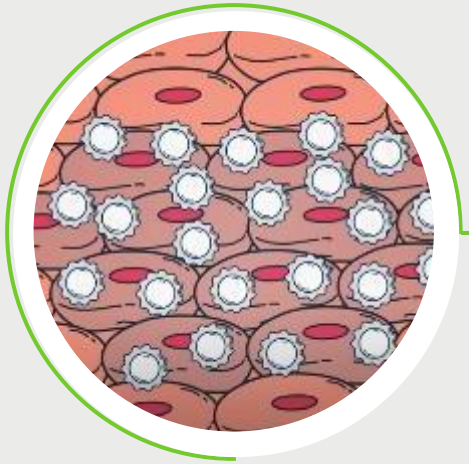
FluoGuide-powered precision surgery: Proprietary uPAR probe

Fluorescent Probe FG001

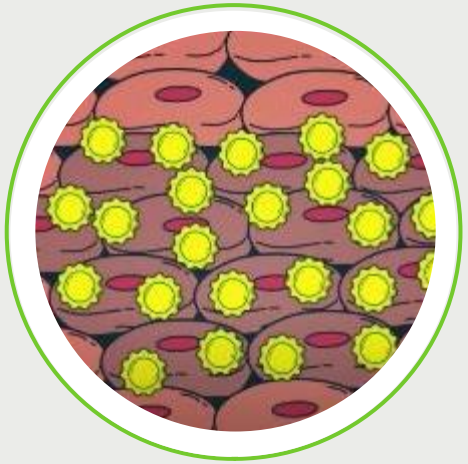
Injected prior to surgery



Binding to cancer



Guiding during surgery



Source: FG001-CT-001, data on file

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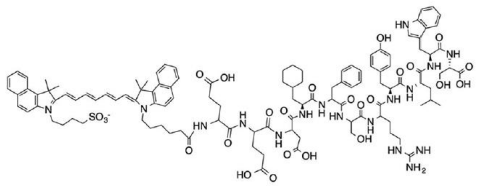
FG001 – a uPAR targeted imaging agent

1. FG001 binds to uPAR

- Binds to uPAR after i.v. administration
- uPAR's cancer specificity and low systemic expression ensure targeted tumor fluorescence

FG001

A uPAR binding peptide covalently bound to a fluorescent molecule*)

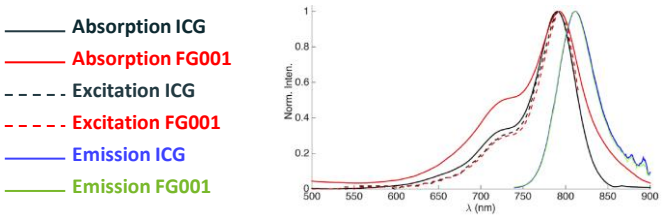


ICG-Glu[1]-Glu[2]-Asp[3]-Cha[4]-Phe[5]-(D)ser[6]-(D)arg[7]-Tyr[8]-Leu[9]-Trp[10]-Ser[11]

2. Robust pre-clinical data demonstrated safety and feasibility

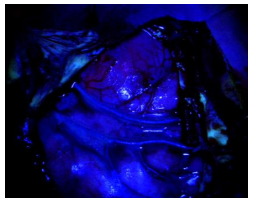
- Based on well-known components – ICG is approved in US since 1959 with good safety data
- Well tolerated - No-observed-adverse-effect-level dose (NOAEL) defined by feasibility

3. FG001 same spectral characteristics as ICG (device agnostic)

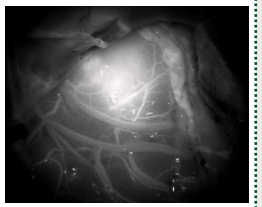


4. Near-infrared light leads to deeper tissue visibility

1. generation (5-ALA) **1-2 mm**



2. generation (FG001) **1-2 cm**



Sources NDA011525, FG001-CT-001, data on file, Juhl K et al (2016) PLoS ONE 11(2)
*The fluorescent molecule is indocyanine green

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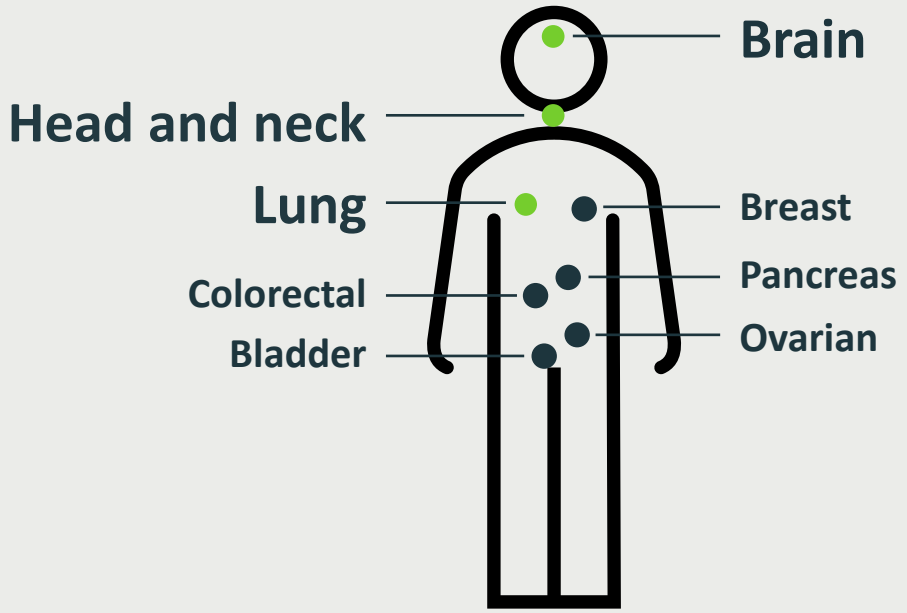
Unique uPAR-targeting technology platform

uPAR plays a central role in cancer invasion

- uPAR (**urokinase-type plasminogen activator receptor**) is a cell membrane receptor that plays a key role in proteolytic activity
- **Highly specific** & extensively expressed in solid cancers, associated with poor prognosis and metastatic dissemination
- Expression in the invasive **front of the tumor**, enables precise removal of cancer tissue
- Expression is **proportional to cancer aggressiveness**
- Recognised target supported by a large scientific body[1]

>80% of solid cancers express uPAR



Source: Metrangolo V, Ploug M, Engelholm LH. The Urokinase Receptor (uPAR) as a "Trojan Horse" in Targeted Cancer Therapy: Challenges and Opportunities. Cancers (Basel). 2021 Oct 27;13(21):5376. doi: 10.3390/cancers13215376. PMID: 34771541; PMCID: PMC8582577.

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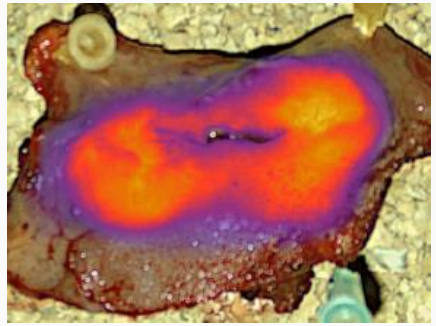
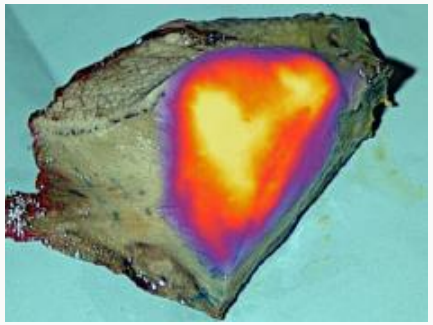
uPAR expression and FG001 binding to cancer

Macro imaging

Fresh tissue

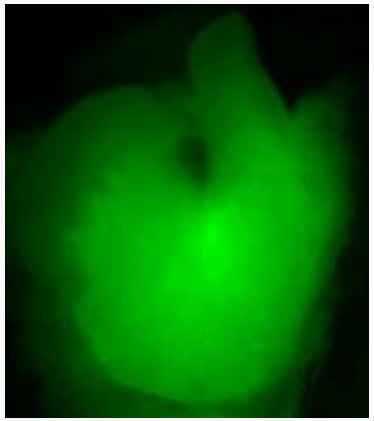


Formalin fixed tissue



Micro imaging

FG001



H&E

uPAR

Source: International Academy of Oral Oncology (IAOO), 2023 Incheon, South Korea, Christensen, A et al

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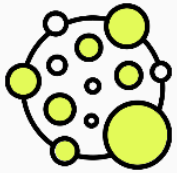
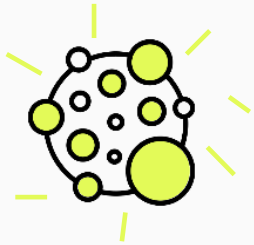
Therapeutic applications with uPAR targeted photothermal treatment (FG001)

1 | FG001 binds to uPAR



2 | FG001 is excited with light of specific wavelength



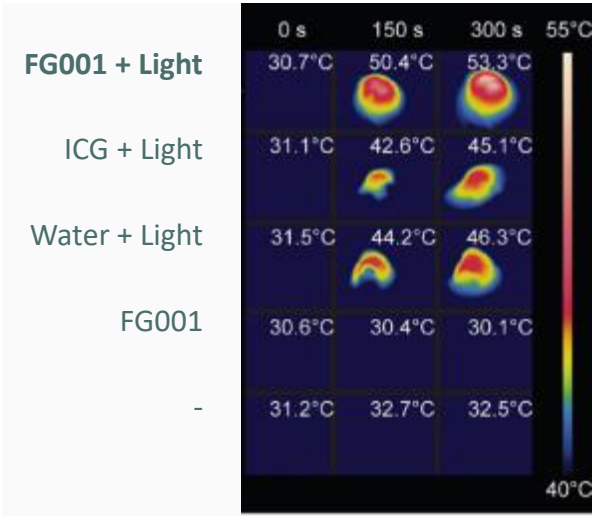
3 | FG001 releases energy in the form of light emission and heat

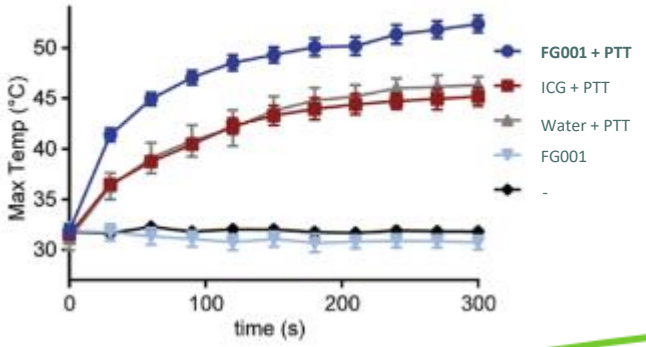
Photothermal therapy is a cancer treatment that induces cancer cell death by heat generated in tumor tissue exposed to near-infrared light

FG001 has the potential to act as a near-infrared light absorbent to facilitate efficient and targeted cancer cell heat destruction

Shown to prolong survival in a mouse xenograft glioblastoma model

Temperature in cancer cells





Source: Simón et al, Oncotarget, 2021 Jul 6;12(14):1366-1376

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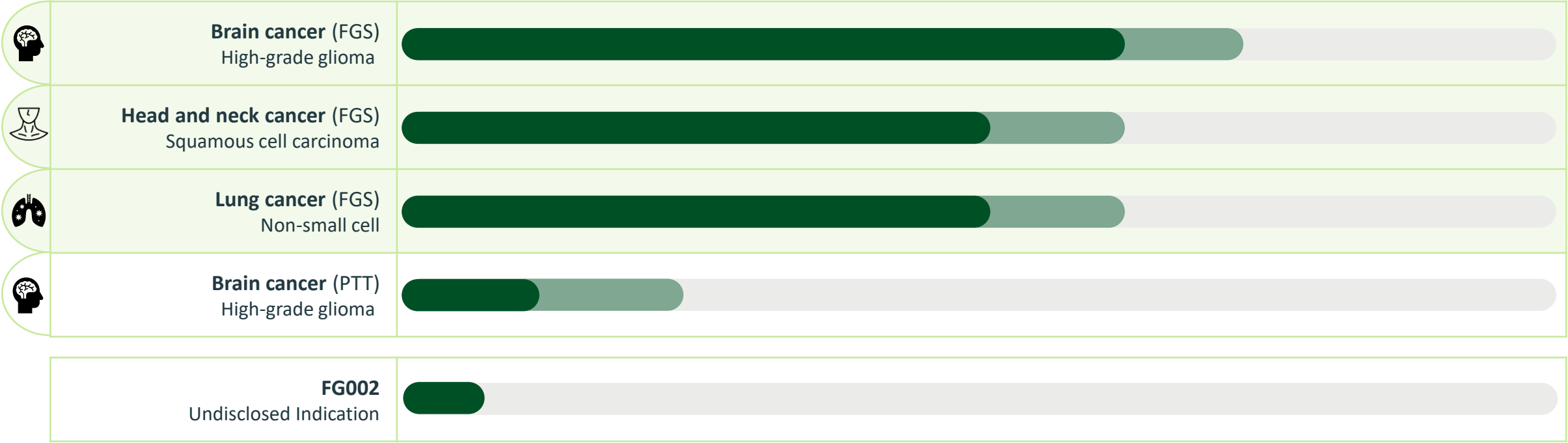
Advanced pipeline

INDICATION	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
FG001				
Brain cancer (FGS) High-grade glioma				
Head and neck cancer (FGS) Squamous cell carcinoma				
Lung cancer (FGS) Non-small cell				
Brain cancer (PTT) High-grade glioma				
FG002 Undisclosed Indication				



FGS (Fluorescent guided surgery); PTT (Photothermal Therapy); TBR (Tumor to background ratio, a measurement of contrast)

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The surgeon’s dilemma: balancing disability risk and cancer recurrence

The **cavity** after removal of obvious cancerous tissue

*“Do I risk to **remove too much** and disable the patient?”*

*“Do I risk to **leave cancer behind** leading to recurrence of the cancer?”*

Malignant brain cancers

- Cancer recures months after surgery (approx. 50% in 14 months)
- Adverse events from surgery impact post surgery treatment

Non-malignant brain cancers

- Cancer recures years after surgery (9% in 10 years)
- Adverse events from surgery persist thought out the life (20% has adverse events post surgery)

The solution: More precise surgery

✓ **Detect and remove additional cancer**

✓ **Spare critical functions**

1) Ostrom, Q., Gittleman, H., Liao, P., Rouse, C., Chen, Y., & Dowling, J. et al. (2014). CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2007-2011. Neuro-Oncology, 16(suppl 4), iv1-iv63. doi: 10.1093/neuonc/nou223

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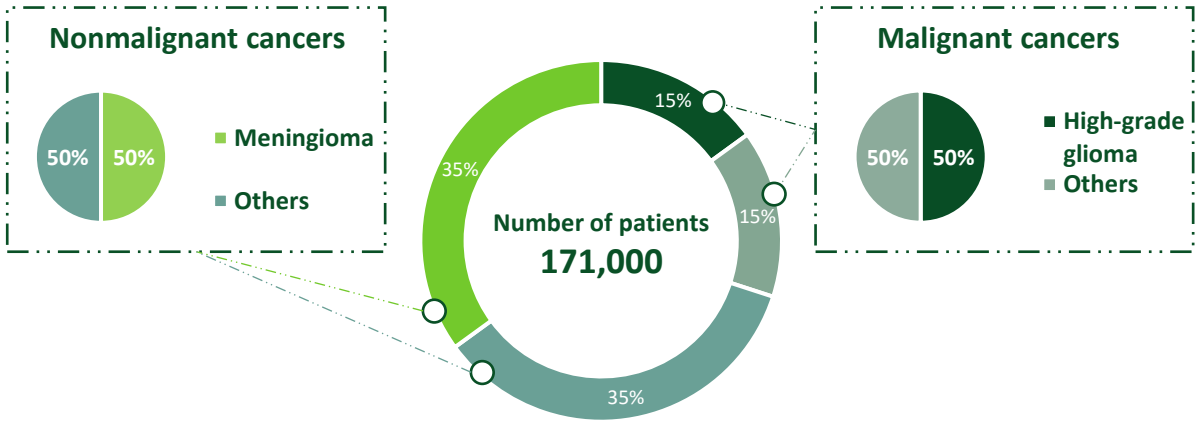
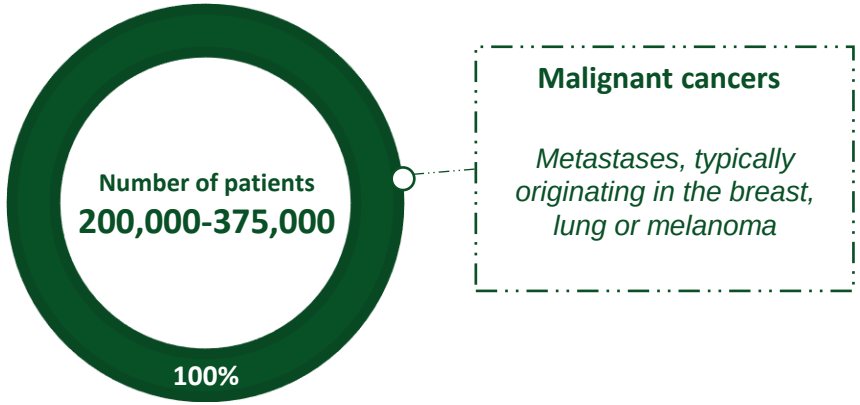
Precise tumor resection improves patient outcomes in brain cancers

Primary cancers



	Incidence per 100,000	New patients/year in US & EU
Malignant cancers	7.0	51,000
Nonmalignant cancers	17.0	120,000

Secondary cancers



	Incidence per 100,000	New patients/year in US & EU
Metastases	30-52	200,000-375,000

Source: (1) Miller KD et al. Brain and other central nervous system tumor statistics, 2021. CA Cancer J Clin. 2021 Sep;71(5):381-406 (2) Amsbaugh MJ et l. Brain Metastasis. 2023 Apr 3 StatPearls Publishing; 2023 Jan (3) Holleczek B et al. Incidence, mortality and outcome of meningiomas: A population-based study from Germany. Cancer Epidemiol. 2019 Oct (4) Oya S et al. Nation-wide Brain Tumor Registry-based Study of Intracranial Meningioma in Japan. Neurol Med Chir (Tokyo). 2021 Feb 15;61(2):98-106

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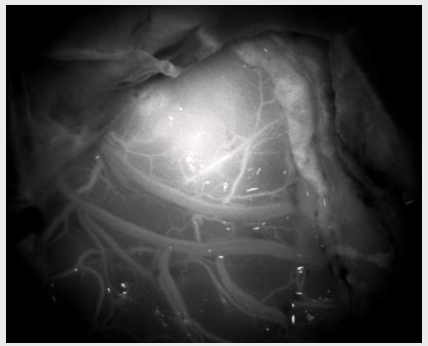
Aggressive brain cancer

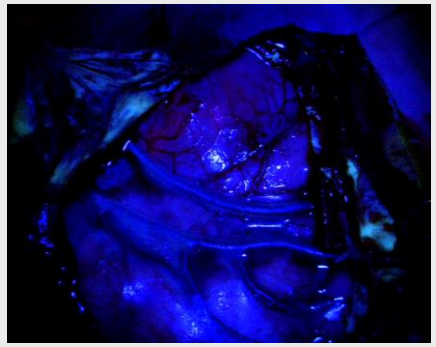
	Phase I/II	Phase II
Status	Top line results presented	
Inclusion	Patients with suspected high-grade glioma undergoing surgery	
#	40	24
Primary endpoint	Safety and tolerability of FG001 and dose finding	Patients with at least one indeterminated tissue or unexpected fluorescent tissue at the end of surgery
Drug	FG001 and 5-ALA were co-administered in all patients	Randomization 1:1 between FG001 or 5-ALA (12 patient on each)
FG001 dose	Dose escalation from 1 mg to 48 mg per patient	36 mg per patient the evening before the surgery

Trial results (FG001-CT-001)

1. **All patients receiving FG001 (12/12) had additional cancer detected showing FG001 was superior to white light**. The result for 5-ALA was 12/12.
2. **No statistically significant differences between FG001 and 5-ALA in accuracy or gross total resection (MRI)**
3. **FG001 lit up in all patients (41)**
   dosed at 8mg or higher.
4. **FG001 was safe and well tolerated in all patients with 2 related AEs (grade 1)**
   The result for 5-ALA was 10 related AEs (8 grade 1 and 2 grade 2).
5. **FG001 visualize tumor on dura prior to incision in 4/12 patients (deeper visualization)**.
   The result for 5-ALA was 0/12.

FG001





5-ALA

Source: FG001-CT-001, data on file

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Phase I/II key result: FG001 is well tolerated and works in HGG

Outstanding safety profile

0 Serious related AEs

4 Related mild AEs

Grade 1: n=3
Grade 2: n=1

No Dose Limiting Toxicities

Clinical data confirm outstanding tolerability profile shown in pre-clinical testing

Optimal dose with 36 mg FG001

8 mg — Consistent visualisation starting from 8 mg

36 mg — **High contrast images across imaging equipment at 36 mg**

48 mg — Optimal TBR identified at 36 mg
No DLTs observed

Histopathology confirmed results*)

Specificity: 100%
(CI 59-100%)

"All tissue samples lighting up contain only cancer"

* N= 33, excluding 2 samples from necrotic tumor core

Source: FG001-CT-001, data on file

Primary endpoint in phase II supporting regulatory approval

Primary end-point	FG001	5-ALA
Additional cancer tissue removed[1)]	**12 / 12 (100 %) patients** (CI: 73.5;100)	**12 / 12 (100 %) patients** (CI: 73.5;100)

FG001 met primary end-point in phase II

[1)] Proportion of patients with indeterminated or unexpected fluorescence tissue at the end of surgery and verified cancer positive by histopathology
Source: FG001-CT-001, data on file

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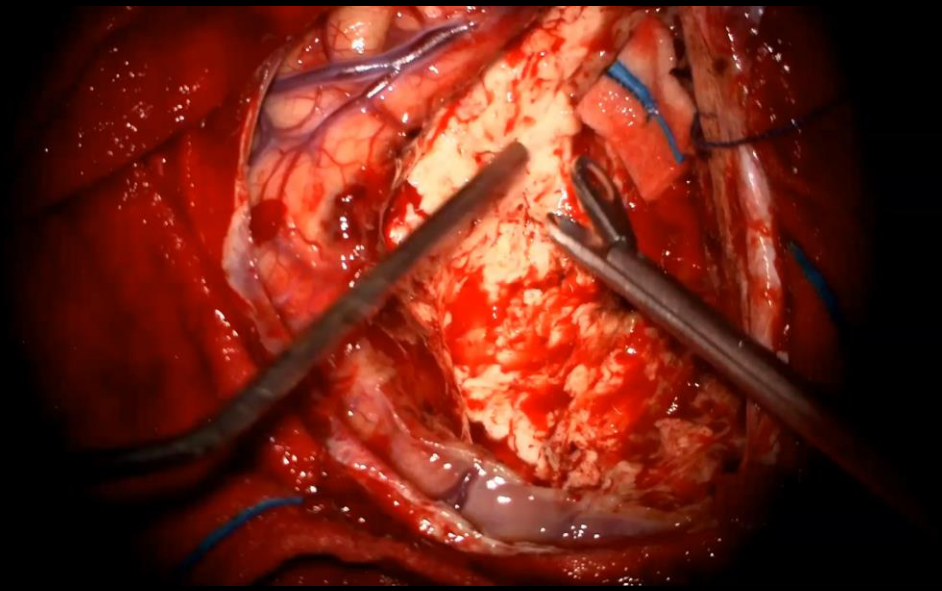
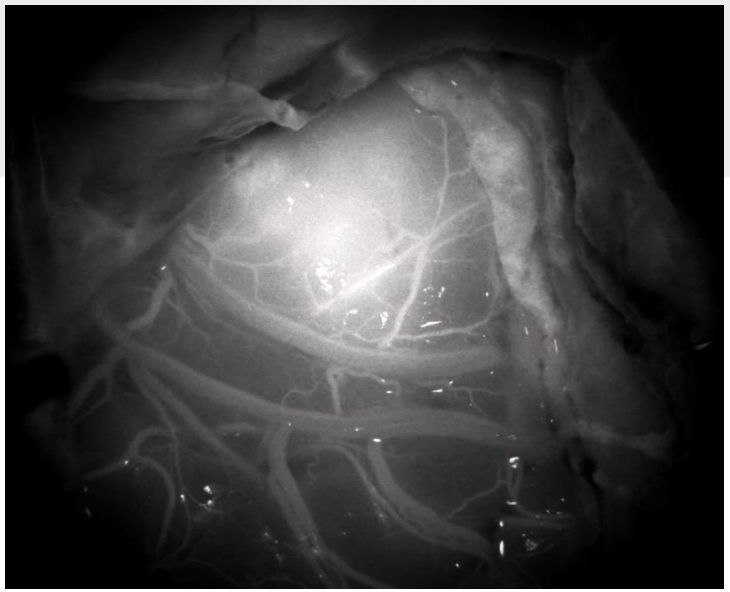
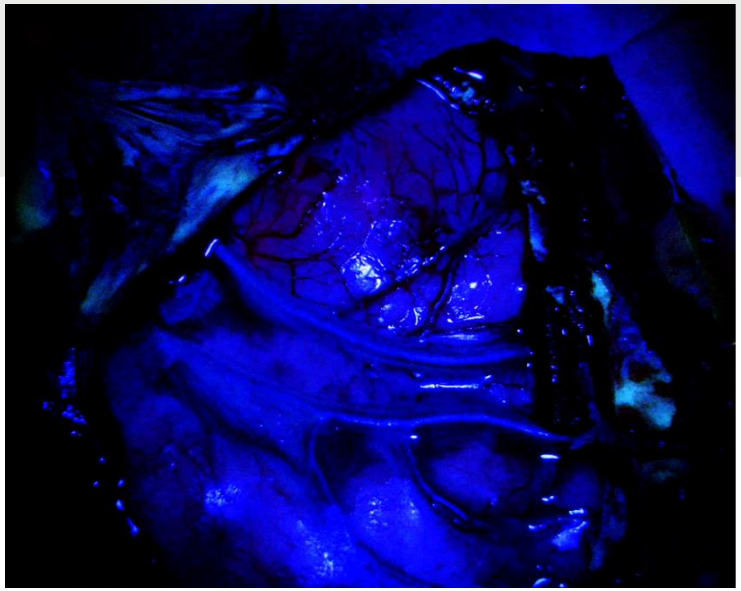
Transition zone (Primary Endpoint biopsy sampling - cancer)



FG001 - deep visualization of cancer

Phase I/II	FG001	5-ALA
Fluorescence visualization of tumor after removal of dura and prior to incision (same patient)		

Phase II	FG001	5-ALA
Fluorescence visualization of tumor on dura prior to incision	**4 / 12 (33 %) patients**	**0 / 12 (0%) patients**

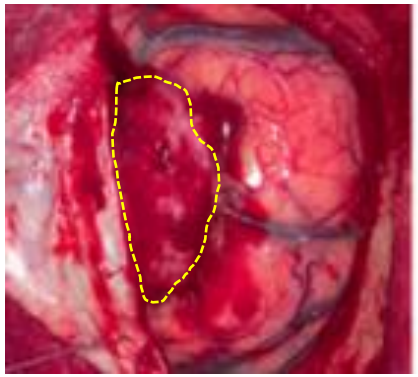
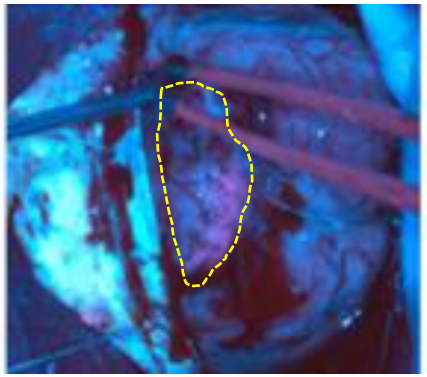
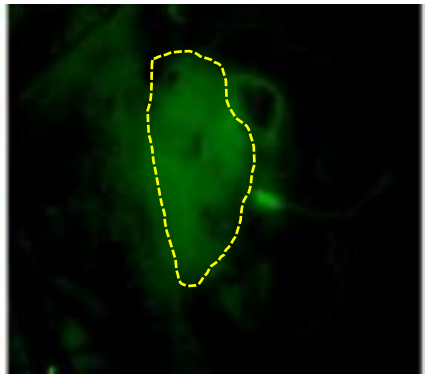
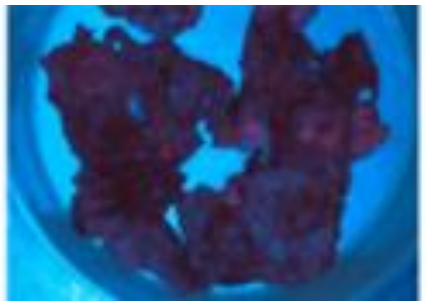
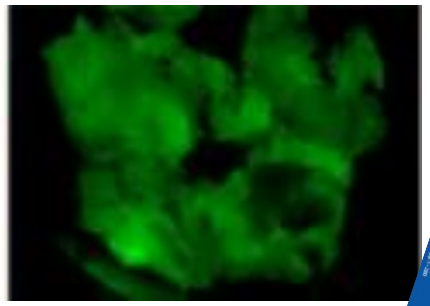
Source: FG001-CT-001, data on file

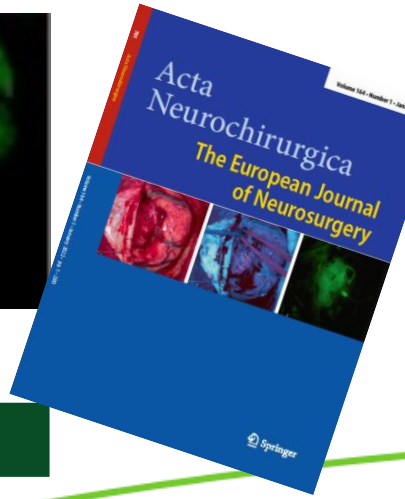
FG001 is well tolerated

Related Adverse Events	FG001 N=12	5-ALA N=12
Serious Related Adverse Events	0	0
Related Adverse Events	**2**	**10**
Severity grading of Related Adverse Events:		
Grade ≥ 3	0	0
Grade 2	0	**2**
Grade 1	**2**	**8**

Source: FG001-CT-001

FG001 demonstrated signs of clinical efficacy in meningioma

Both FG001 and 5-ALA were administered prior to surgery	Nothing ("white light")	5-ALA ("blue light")	FG001 ("NIR light") (8mg low dose)
Brain before surgery (cancer marked):			
Cancer tissue after removal:			



FG001's potential in brain cancer goes potentially beyond high grade glioma aggressive brain cancer

Source: Skjøth-Rasmussen et al, Acta Neurochir, 2022 Jan;164(1):267-271.

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Compatibility with existing systems enables fast adoption by clinical practice

Compatible with existing imaging systems

Microscope

Visualisation of small structures, e.g., brain and head & neck

Potential partnerships

Typically used in:
Brain

ZEISS Leica OLYMPUS

Several surgical lasers could work with PTT

Laser

Multiple applications in surgery

Potential partnerships

Used in:
All types of surgery

Several plays are involved in the surgical laser market; eg. Cynosure, Lumenis, IPG Photonics Corporation, biolitec AG, Alma Lasers Ltd, Boston Scientific Corporation, BISON Medical, Candela Corporation, Biolase, Cutera, Inc., Alcon, and Fotona

The microscope market for fluorescence guided surgery (FGS) is mature and dominated by few players.
The market for laser surgery for not established and multiple companies develop and sell lasers for surgical applications

Source: https://www.mordorintelligence.com/industry-reports/surgical-lasers-market

Feedback from FDA

FDA's feedback on FG001 in high grade glioma

1. Exposure to ≥300 patients to provide evidence of safety for first indication. Pooling across trials gives flexibility in the trial design.
2. Completeness of resection seems acceptable end-point.
3. 6 and 12 months follow up is suggested.

*Including **photothermal therapy** in the regulatory trial is anticipated to require a **slight increase** in terms of number of patients and duration compared to the clinical program necessary for supporting fluorescent guided surgery*

Source: Data on file

Plans for FG001 in brain cancer 2024

1 | Expand the label of FG001 in HGG expanding the commercial potential

- Initiate phase II trial
- Assessing the potential of photothermal therapy (PTT) in aggressive brain cancer (HGG)
- Expanding support for reimbursement
- Expanding usability, e.g. flexibility in time of FG001 administration

2 | Evaluate inclusion of PTT in the label of FG001 based on the result

3 | Obtain FDA feedback on phase III clinical end-point

4 | Expand documentation for safety and efficacy

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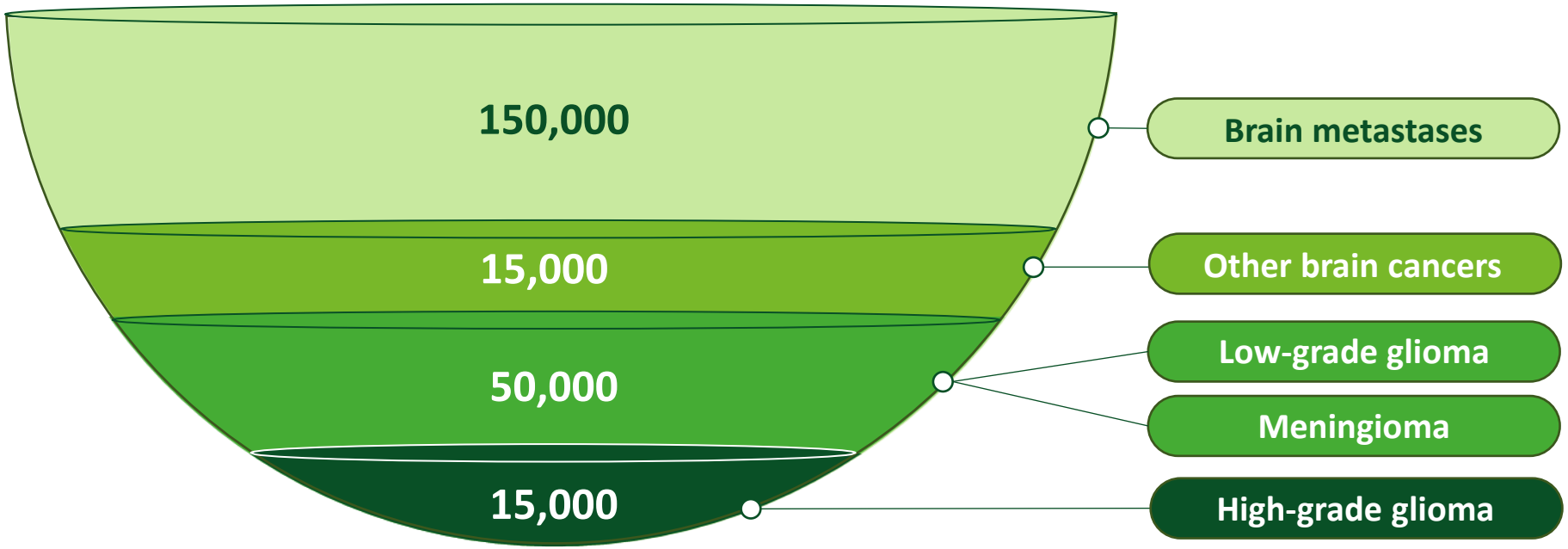
More than 230,000 patients gets diagnosed with brain cancer each year

Potential to expand across geographies

Brain cancer patients in US



Potential of photothermal therapy

The potential of photothermal therapy gives access to additional expansion across treatments, associated with new market opportunities

1) Ene CI and Ferguson SD (2022) Surgical Management of brain Metastasis: Challenges and Nuances. Front. Oncol. 12:847110. doi: 10.3389/fonc.2022.847110; 2) Ostrom et al. Neuro Oncol, 2017; 3) Amsbaugh MJ, Kim CS. Brain Metastasis. [Updated 2023 Apr 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470246/

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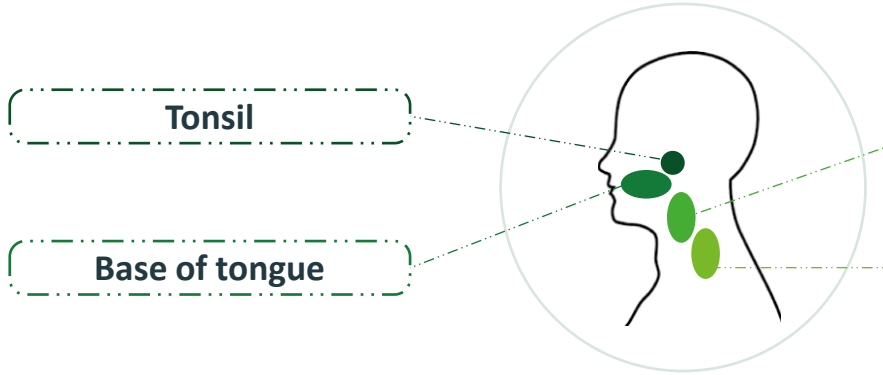
The challenges in head and neck cancer surgery

"Near margin" *cause* ***re-surgery, chemo- and radiotherapy***



"Difficult to reach" *cause* ***chemo- and radiotherapy***

The solution: More precise surgery

- ✓ **Check for margins during surgery**
- ✓ **Enable reachability by minimal invasive surgery**

Source: (1) Gal TJ et al. Treatment trends in oropharyngeal carcinoma: Surgical technology meets the epidemic. Oral Oncology, Vol 97, 2019, p 62-68 (2) Cramer JD et al. The changing therapeutic landscape of head and neck cancer. Nat. Rev. Clin. Oncol. 16, 669–683 (2019); *) Eligible defined by WHO reduced from 680,000

FluoGuide

Precise tumor resection enables close margins & reachability

Oroharynx cancer

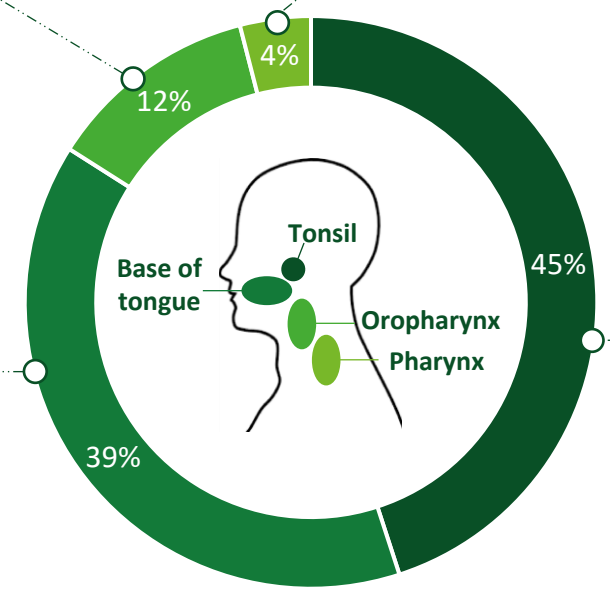
New patients pr year

US & EU	Rest of the world
≈37,000	≈24,000

Pharynx cancer

New patients pr year

US & EU	Rest of the world
≈13,000	≈8,000



Tongue cancer

New patients pr year

US & EU	Rest of the world
≈125,000	≈82,000

Tonsil cancer

New patients pr year

US & EU	Rest of the world
≈142,000	≈94,000

Source: (1) Gal TJ et al. Treatment trends in oropharyngeal carcinoma: Surgical technology meets the epidemic. Oral Oncology, Vol 97, 2019, p 62-68 (2) Cramer JD et al. The changing therapeutic landscape of head and neck cancer. Nat. Rev. Clin. Oncol. 16, 669–683 (2019); *) Eligible defined by WHO reduced from 680,000

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Head and neck (FG001-CT-003)

	Phase II
Status	Top line result presented
Inclusion	Oral and oropharyngeal squamous-cell carcinoma scheduled for surgery
#	16
Primary endpoint	Sensitivity (PoC)
Drug	FG001
FG001 dose	4, 16, 36mg per patient the evening before the surgery

Trial results

1. **FG001 shown relevant contrast (TBR) in all patients (16)**
2. **FG001 was safe and well tolerated in all patients**

Normal image as the surgeon sees it when checking for local metastasis.

Source: FG003-CT-001, data on file

Head and neck (FG001-CT-003)

	Phase II
Status	Top line result presented
Inclusion	Oral and oropharyngeal squamous-cell carcinoma scheduled for surgery
#	16
Primary endpoint	Sensitivity (PoC)
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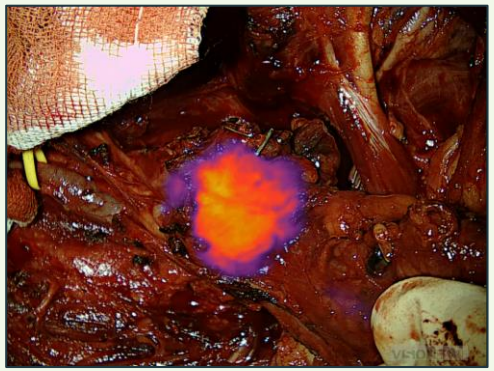
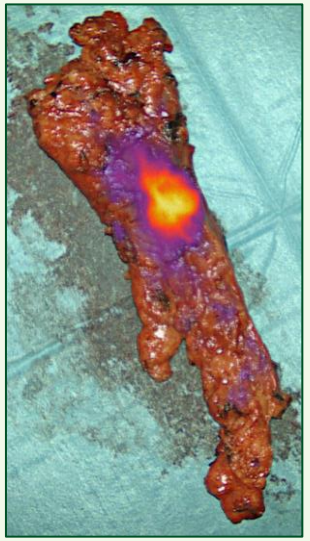
Trial results

1. **FG001 shown relevant contrast (TBR) in all patients (16)**
2. **FG001 was safe and well tolerated in all patients**

After the near Infrared (NIR) light is switched on. A metastasis (lymph node) is clearly seen.





Source: FG003-CT-001, data on file

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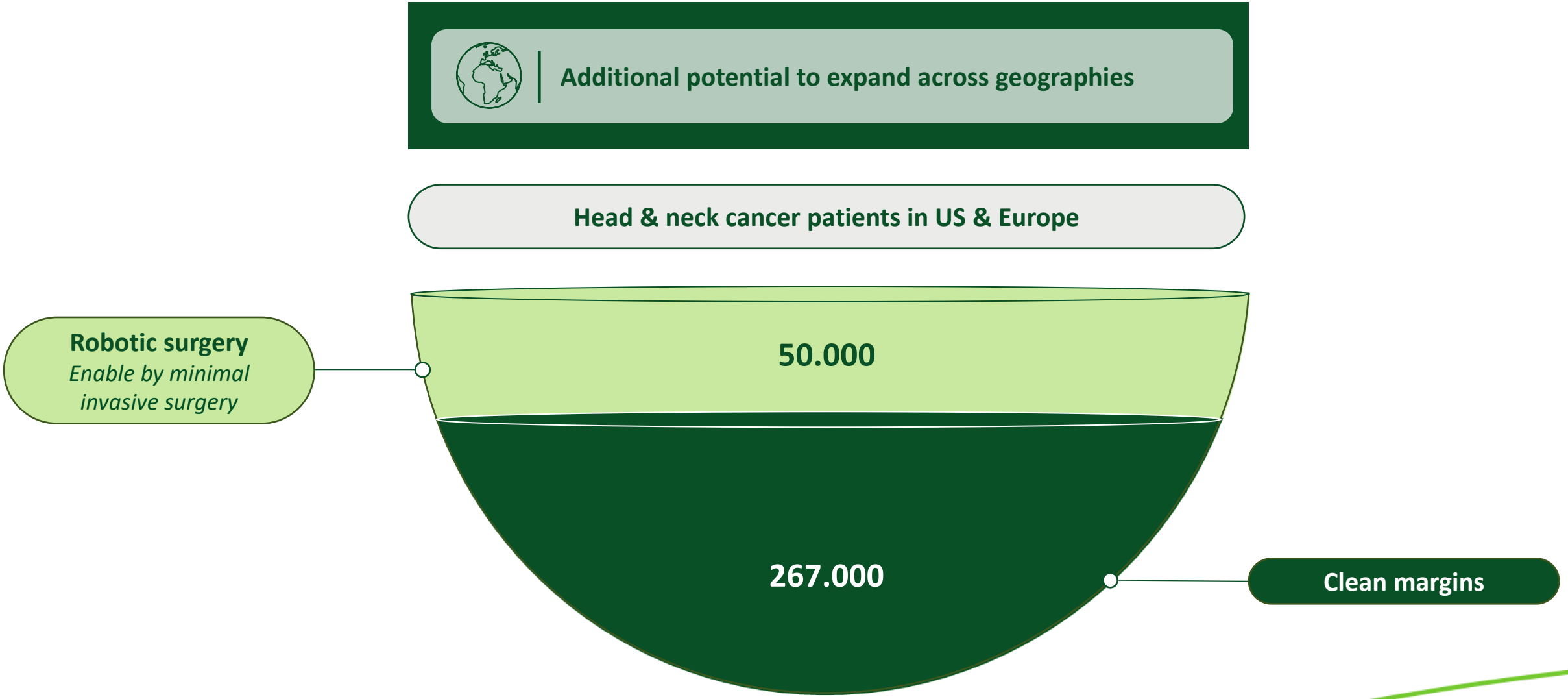
The initial focus is margins and use of robotic equipment in H&N



1) Ene CI and Ferguson SD (2022) Surgical Management of brain Metastasis: Challenges and Nuances. Front. Oncol. 12:847110. doi: 10.3389/fonc.2022.847110; 2) Ostrom et al. Neuro Oncol, 2017; 3) Amsbaugh MJ, Kim CS. Brain Metastasis. [Updated 2023 Apr 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470246/

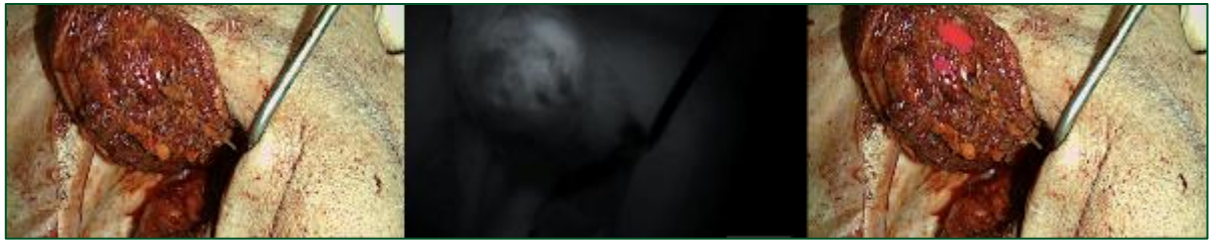
FluoGuide

A range of opportunities for the patients and hospitals

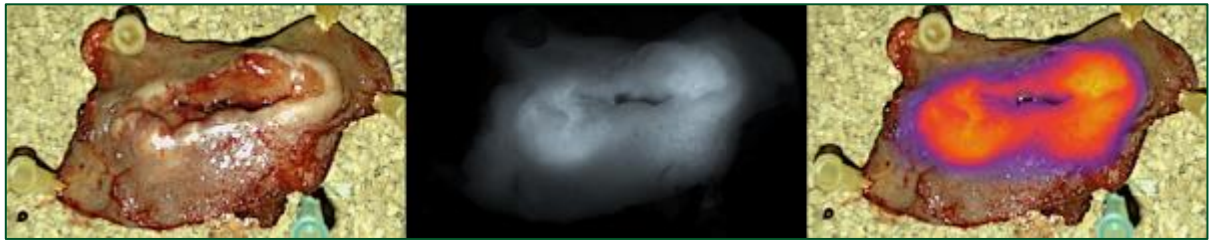
Potential clinical benefits

- **Pre-operative planning of surgery:**
  - Spare hospital time,
  - Spare tung and speech function and
  - Improve cosmetic result
- **Reduce and/or immediately check margins for cancer [1)]**
  - Avoid local recurrence of the cancer
  - Spare hospital time
  - Spare re-surgery and more aggressive post-surgery treatment (chemo- and radiotherapy)
- **Find local metastasis [2)]**
  - Identify local spread and positive lymph nodes during surgery
- **Watchful waiting:**
  - Screening for oral cancers
- **Enable surgical treatment of pharyngeal cancer:**
  - Enabling use of new equipment

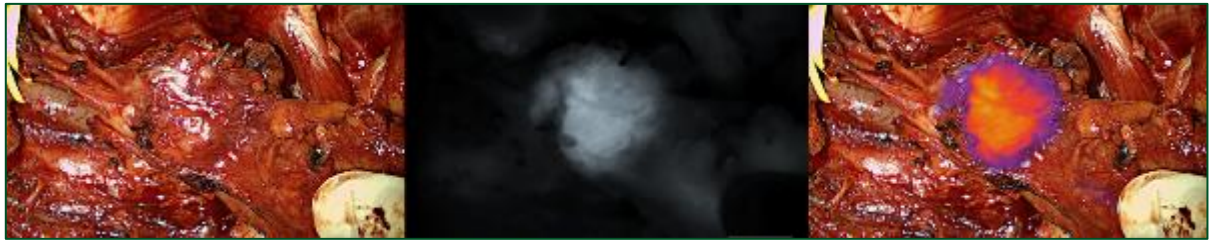
[1)] Resection Cavity



[1)] Back-table image of the tumor



[2)] Tumor metastasis during surgery



Source: Poster "Optical-Guided Surgery in Patients with Oral and Oropharyngeal Squamous Cell Carcinoma (OSCC & OPSCC) Using a Novel uPAR-targeting Near-Infrared Imaging Agent FG001: An Explorative Phase II Clinical Trial – a Case Example" (presenter: Dr. Amanda Øster Andersen, PI: Dr. Anders Christensen both from Rigshospitalet) presented at the World Molecular Imaging Congress (WMIC) 2023 in Prague

Head and neck cancer surgery offers multiple potential partnerships

Compatible with existing imaging systems

Microscope and open field
Visualisation of small structures or superficial cancers

Endoscope
Flexible for visualisation and operation inside the body

Robot
Allows multiple arms and remote control

Back table histology
Allow fast feedback to surgeons

Potential partnerships

Penetrated in e.g. brain surgery useful in other types of surgery	ZEISS, Leica, OLYMPUS
Penetrated in GI or lung surgery useful in other types of surgery	OLYMPUS, ETHICON a Johnson & Johnson company, Johnson & Johnson, STORZ KARL STORZ – ENDOSKOPE, Boston Scientific, Medtronic
Penetrated in urological surgeries useful in other types of surgeries	INTUITIVE SURGICAL, stryker, Johnson & Johnson, Medtronic
Several vendors' system are used broadly	Several vendors

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Plans for FG001 in head & neck cancer in 2024

1 | Advance development of FG00 toward registration in head & neck cancer

- Initiate phase ll trial
- Determine multiple positioning of FG001 in head & neck cancer
- Expanding possible partnership opportunities
- Expanding support for reimbursement

2 | Explore different clinical end-points and regulatory feedback

3 | Expanding commercial opportunities

4 | Expanding partnership opportunities

FluoGuide

Market potential and approach

Brain cancer market potential

1 | The neurosurgeon's challenge of removing **too much** vs. **leaving cancer behind** can be solved with **precision surgery** through detection & removal and at the same time **sparring normal tissue.**

2 | More than **230,000 people/year** are diagnosed with **brain cancer** in the US alone, representing by a small customer group (**neurosurgeons**). Europe and rest-of-the-world represent significant additional potential.

3 | Expanding benefit and price potential with **photothermal therapy**, creates significant additional opportunity.

4 | **Compatibility with existing equipment** enables **faster adoption** and integration.

Head & neck cancer market potential

1 | Precision surgery can solve the challenges **of near-margin** and **difficult to reach** anatomies in head & neck cancer (pharynx and oropharynx).

2 | More than **317,000 people/year** are diagnosed with head & neck cancer in Europe and US together, divided on tongue, tonsil, pharynx and oropharynx.

3 | FG001 offers several **valuable positionings** to the benefit of patients with head & neck cancer.

4 | **Compatibility with existing equipment** opens for partnership with various equipment manufacturers of **microscopes, endoscopes, robots,** and **back table histology**.

1) Ene CI and Ferguson SD (2022) Surgical Management of brain Metastasis: Challenges and Nuances. Front. Oncol. 12:847110. doi: 10.3389/fonc.2022.847110; 2) Ostrom et al, Neuro Oncol, 2017; 3) Amsbaugh MJ, Kim CS. Brain Metastasis. [Updated 2023 Apr 3]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470246/

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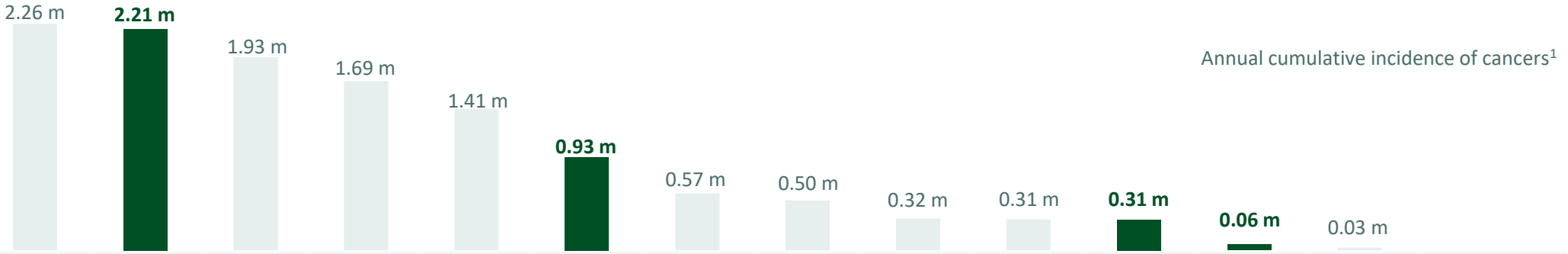
Well-positioned in fluorescence-guided surgery



Company	Breast	Lung	Colorectal	Gastro-intestinal	Prostate	Head & Neck	Bladder	Pancreatic	Melanoma	Ovarian	Brain	Malignant Glioma	Sarcoma	Compatible with existing systems
FluoGuide		**Phase 2a**				**Phase 2a**					**Phase 2a*)**	**Phase 2b**		**√**
SBI Holdings												Approved		(√)
ONTARGET		Approved			Phase 2					Approved				(√)
SurgiMab			Phase 3					Phase 2a						(√)
AVELAS	Phase 3													
BLAZE	Phase 1					Phase 1			Phase 1		Phase 2/3			(√)
LUMICELL	Phase 3			Phase 1	Phase 1			Phase 1			Phase 1		Phase 1	
							Approved							(√)
oncoRNAno	Phase 2a	Phase 2a	Phase 2a	Phase 1	Phase 2a	Phase 2a				Phase 2a				√
VERGENT		Phase 2												√

Cancer specific target expressed on most solid cancer types

Portfolio targeting multiple indications, currently approx. 3.5 million patients annually

Compatibility with existing imaging systems offers large clinical potential

Source: Company homepages, last update Q1-23. *) CTA approved

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Management & Board of Directors

Management Team

MORTEN ALBRECHTSEN
CEO

Takeda · Boehringer Ingelheim

OLE LARSEN
CFO

BAVARIAN NORDIC · bioporto

ANDREAS KJAER
CSO & CMO

minerva IMAGING · MDPI

GRETHE NØRSKOV RASMUSSEN
CDO

ascendis pharma

DORTHE GRØNNEGAARD MEJER
VP Clinical Development

Genmab · larix

Board of Directors

PETER MØRCH ERIKSEN
Chairman of the board

Medtronic · bioporto

MATS THORÈN
Vice Chairman of the board

Handelsbanken

ANDREAS KJAER
Member of the board

minerva IMAGING · MDPI

MICAELA SJÖKVIST
Member of the board

Securitas · Telia

SHOMIT GHOSE
Member of the board

Berkeley Sutardja Center for Entrepreneurship & Technology · BI BioInnovation Institute

MICHAEL ENGSIG
Member of the board

nykode · Takeda

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Key elements in strategy

uPAR target technology
with potential for broadened use in guiding surgery

- Fluorescence guided surgery (FGS) price: approx. USD 5,000 per surgery
- uPAR target in fluorescence guided surgery relevant for high number of patients : ca. 3,500,000 annually
- **Potential to increase the number of patients to help by being cancer specific rather than cancer type specific**

FG001 has the potential to add value

- ICG generates heat when exposed to light, making it eligible for photothermal therapy (PTT)
- Building on pre-clinical PoC for FG001 for PTT, the further clinical potential of PTT is explored during 2024
- **Increase the benefit provided to each patient**

Commercialization is in the preparation stage

- Expanding the label of FG001 in brain cancer
- Head & neck cancer offers multiple options to help patients and partnering opportunities
- **Increase the speed in helping the patients (market penetration)**

1) DSouza, A., Lin, H., Henderson, E., Samkoe, K., & Pogue, B. (2016). Review of fluorescence guided surgery systems: identification of key performance capabilities beyond indocyanine green imaging. Journal Of Biomedical Optics, 21(8), 080901. doi: 10.1117/1.jbo.21.8.080901

Upcoming clinical milestones and news flow

	Archived **until 2023**	Anticipated in **2024**	Anticipated in **2025**
Development	• Demonstrated FG001 to be safe and well tolerated • Proof of concept in aggressive brain, head and neck (OPSCC), and lung (NSCLC) cancer • Clinical end-points defined for phase III in aggressive brain cancer • Orphan drug designation on FG001 in US for aggressive brain cancer • Photothermal therapy grant on €6.6m	• Assessing potential of photothermal therapy (PTT) in aggressive brain cancer • Initiation of head and neck trial testing regulatory end-points and expanding commercial opportunities • Regulatory consultations	• Clinical result of adding PTT into the clinical trial label of FG001 for aggressive brain cancer • Result of head and neck trial • Initiation of clinical trial supporting registration of FG001 in fluorescence guided surgery of aggressive brain cancer
Commercial and corporate	• IPO in 2019 • Listed on Nasdaq First North Stockholm	• Partner collaboration	• Initiation of market access • Additional partner collaborations

Affärsvärlden's 2019 IPO Guiden evaluated 42 Swedish IPOs – hereof 13 micro-cap companies: Best in micro-cap category and Honorary quality award. FBV Danish award for the best share price performance since IPO

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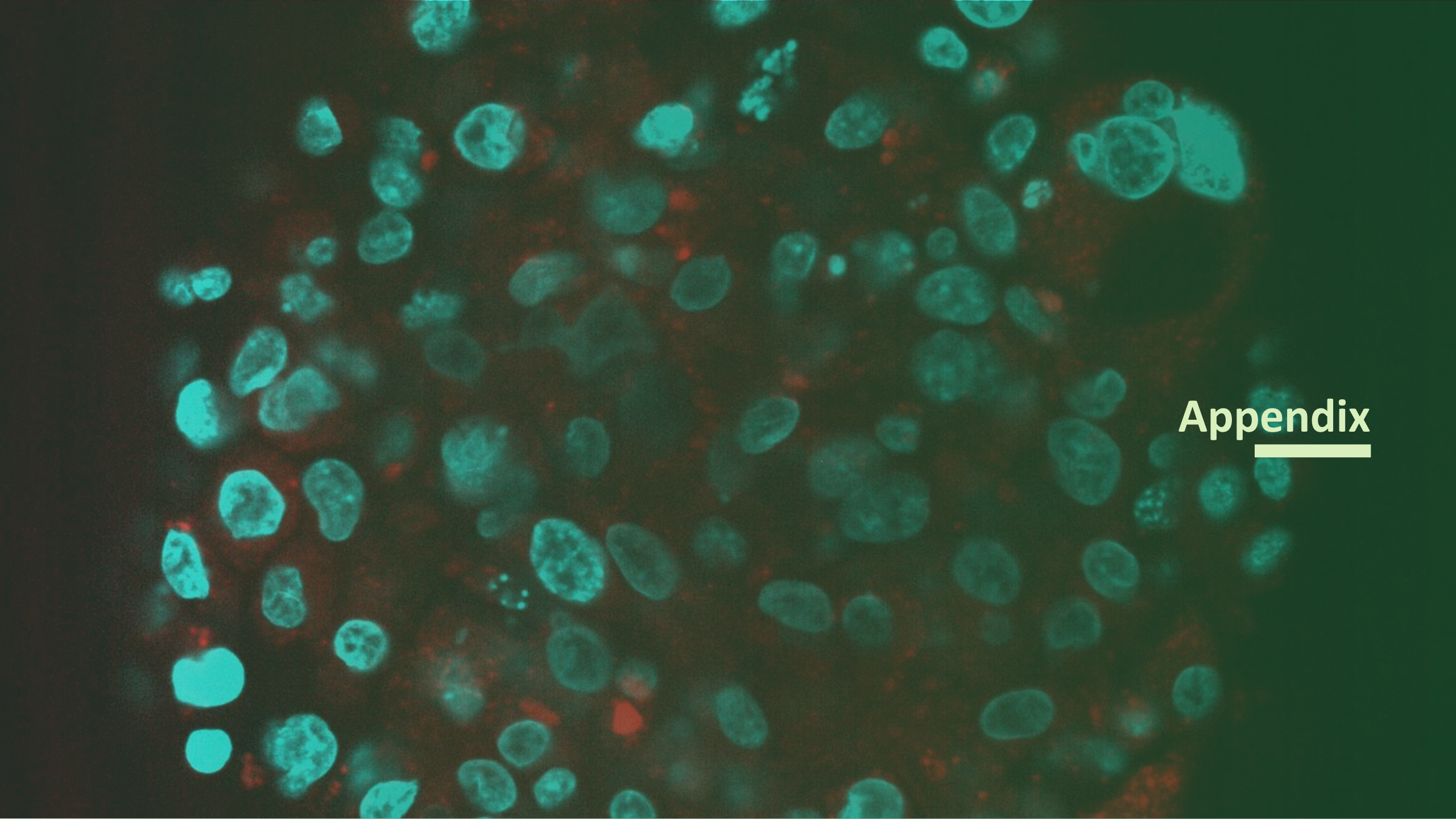
Precision surgery **improving outcome for cancer patients**

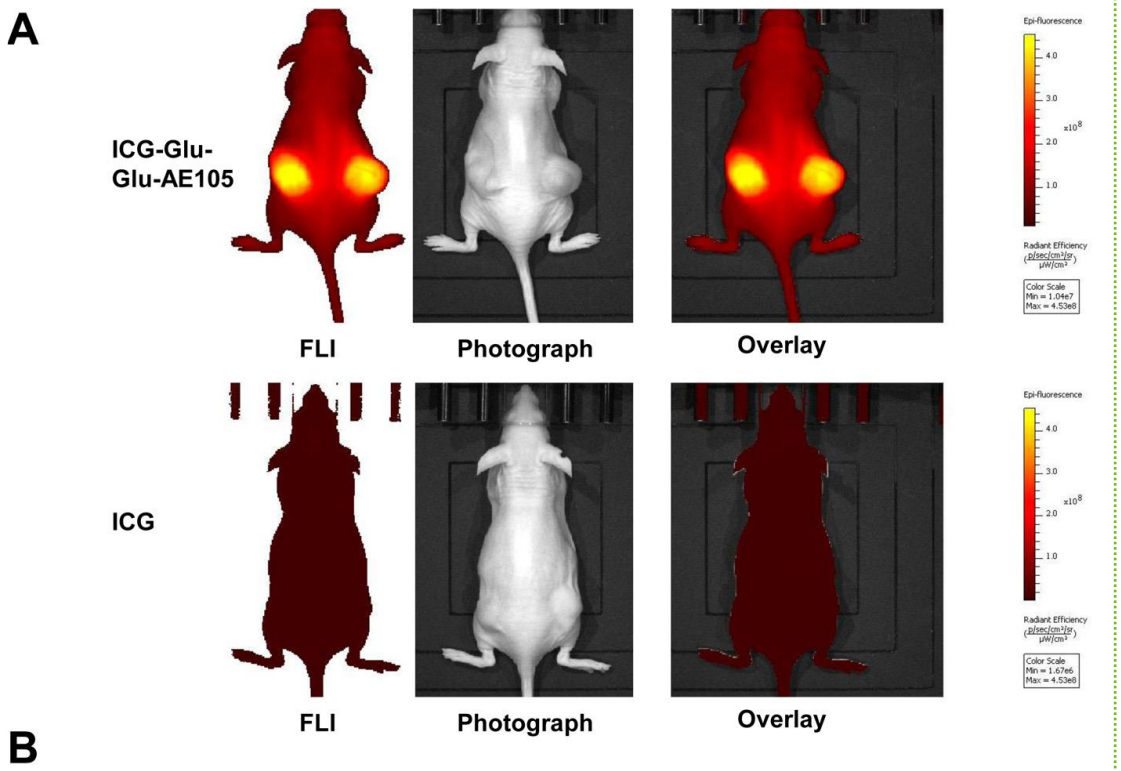


Appendix

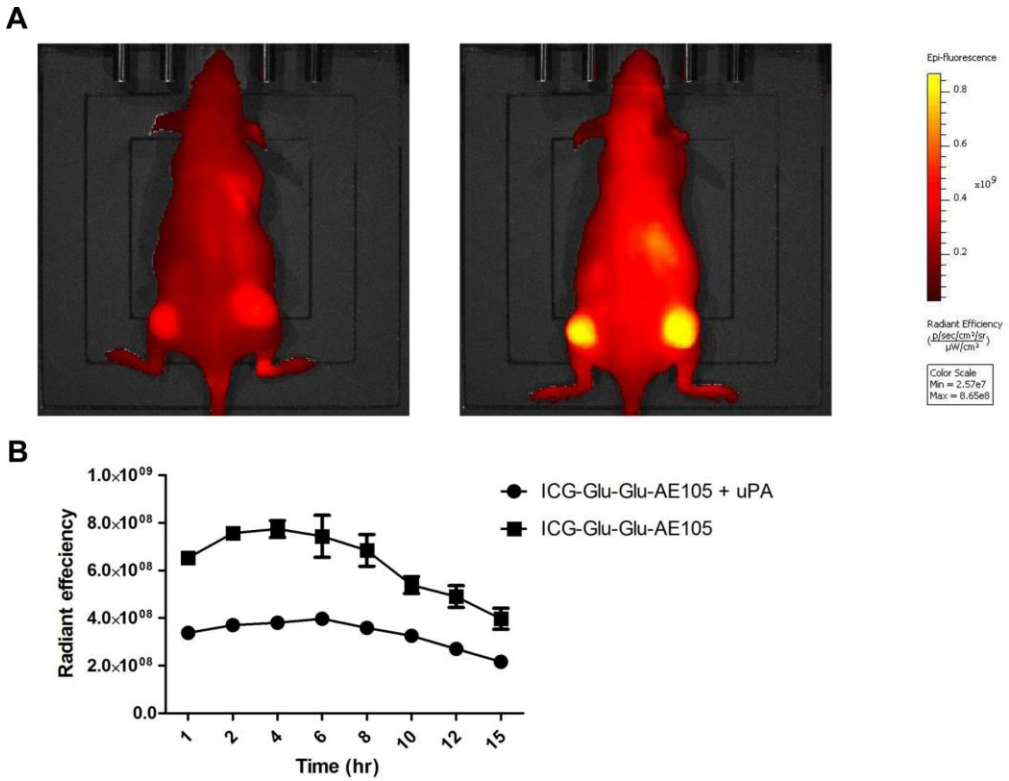
Preclinical model demonstrates FG001s ability to illuminate malignancies

Actively binding to uPAR

Binding – FG001 vs ICG



uPAR specificity (FG001 +/- uPA co-injection)



1) Juhl, K., Christensen, A., Persson, M., Ploug, M., & Kjaer, A. (2016). Peptide-Based Optical uPAR Imaging for Surgery: In Vivo Testing of ICG-Glu-Glu-AE105. PLOS ONE, 11(2), e0147428. doi: 10.1371/journal.pone.0147428

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uPAR expressed in all CNS tumors (including low grade glioma) and predictive for aggressivity

Tumor types and intensity of immunostaining for uPAR

Tumor Type	Grade I - IV	Cases (#)	Average Score 0 = none or same as background, 1+ = weak [trace or slightly perceptible above background], 2+ = moderate, and 3 = strong [same as positive control]
Glial/neuronal tumor types			
Pilocytic astrocytoma	I	5	1.5
Astrocytoma, low grade	II	5	1.6
Anaplastic astrocytoma	III	6	2.2
Glioblastoma	IV	8	2.5
Oligodendroglioma	II	5	2.3
Oligoastrocytoma	II	4	2.5
Anaplastic oligoastrocytoma	III	6	1.9
Ependymoma	II	4	2.7
Ganglioglioma	II	4	2.3
Medulloblastoma	IV	5	2.3
Non-glial tumors			
Meningioma	I	5	2.5
Atypical meningioma	II	2	3.0
Schwannoma	-	6	1.0

Salajegheh M, Rudnicki A, Smith TW. Expression of urokinase-type plasminogen activator receptor (uPAR) in primary central nervous system neoplasms. Appl Immunohistochem Mol Morphol. 2005 Jun;13(2):184-9. doi: 10.1097/01.pai.0000138448.85231.da. PMID: 15894933.

FluoGuide

FG002: uPAR-targeting probe for gastrointestinal tumors

uPAR-targeting probe with a novel fluorophore

FG002 utilises a novel fluorophore - IRDye® 800CW infrared dyes, which have potentially superior brightness

A preclinical study has shown that FG002 illuminates cancer in an orthotopic xenograft model using human glioblastoma cells

FG002 is excreted through kidneys, indicating potential utility in gastrointestinal tumors, such as colorectal cancer

Clinical trials expected to commence in 2024

	FG001	FG002
Development stage	Phase 2b	Preclinical
uPAR binding molecule	AE105	AE344
Dye	ICG	IRDye800CW
Safety support for dye	>50 years on the market	Has been tested in multiple clinical trials
Equipment	All digital solutions	IRDye800 compatible equipment, incl. OTL38
Brightness	++	+++
Elimination /Excretion	Liver	Kidney
Lead indication	Glioblastoma	Gastrointestinal tumors

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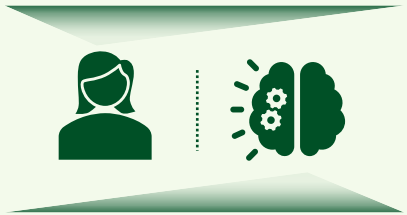
Fibrous meningioma case study: FG001 demonstrated signs of clinical efficacy

A 67y female patient was recruited in the PI/IIa trial on suspicion of malignant glioma, later confirmed to be a fibrous meningioma WHO grade 1 by histology



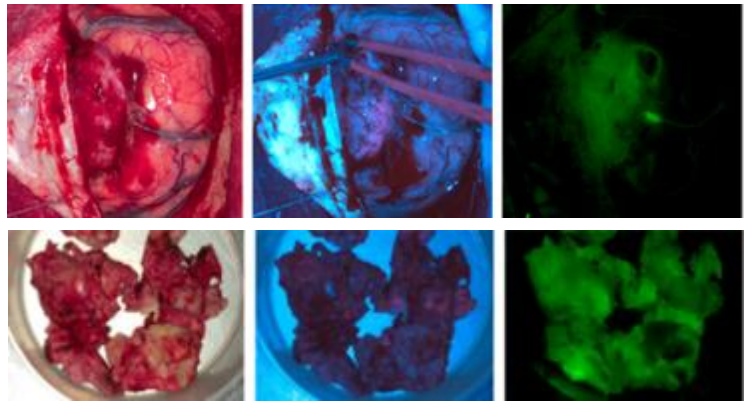
Fibrous meningioma is a benign brain lesion with a significant share of patients experiencing recurrence (20-39%) within 10 years after surgery, while many experience serious surgical side effects

5-ALA
- Oral suspension
- Excitation wavelength 410nm

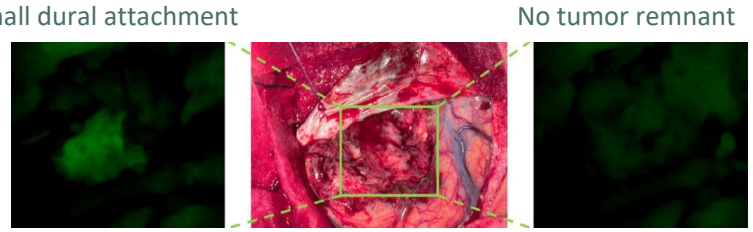
Both 5-ALA and FG001 were administered 6h prior to surgery

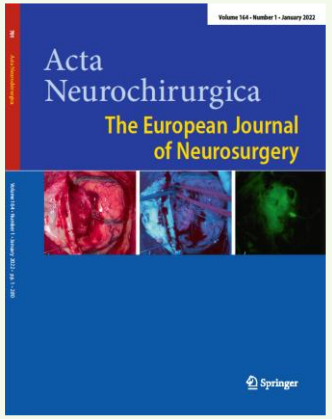
FG001 (8mg)
- Intravenous administration
- Excitation NIR light

High fluorescence signal from FG001 compared to white light and 5-ALA using the same camera



FG001 delineates the tumor both on the surface and in the cavity to help remove dural attachment safely





Results highlighted on front cover of medical journal ***Acta Neurochirurgica*** (Vol. 164, Jan. 2022)

Potential utility in meningioma motivates subsequent clinical trials in a larger patient sample

Source: Skjøth-Rasmussen et al, Acta Neurochir, 2022 Jan;164(1):267-271.

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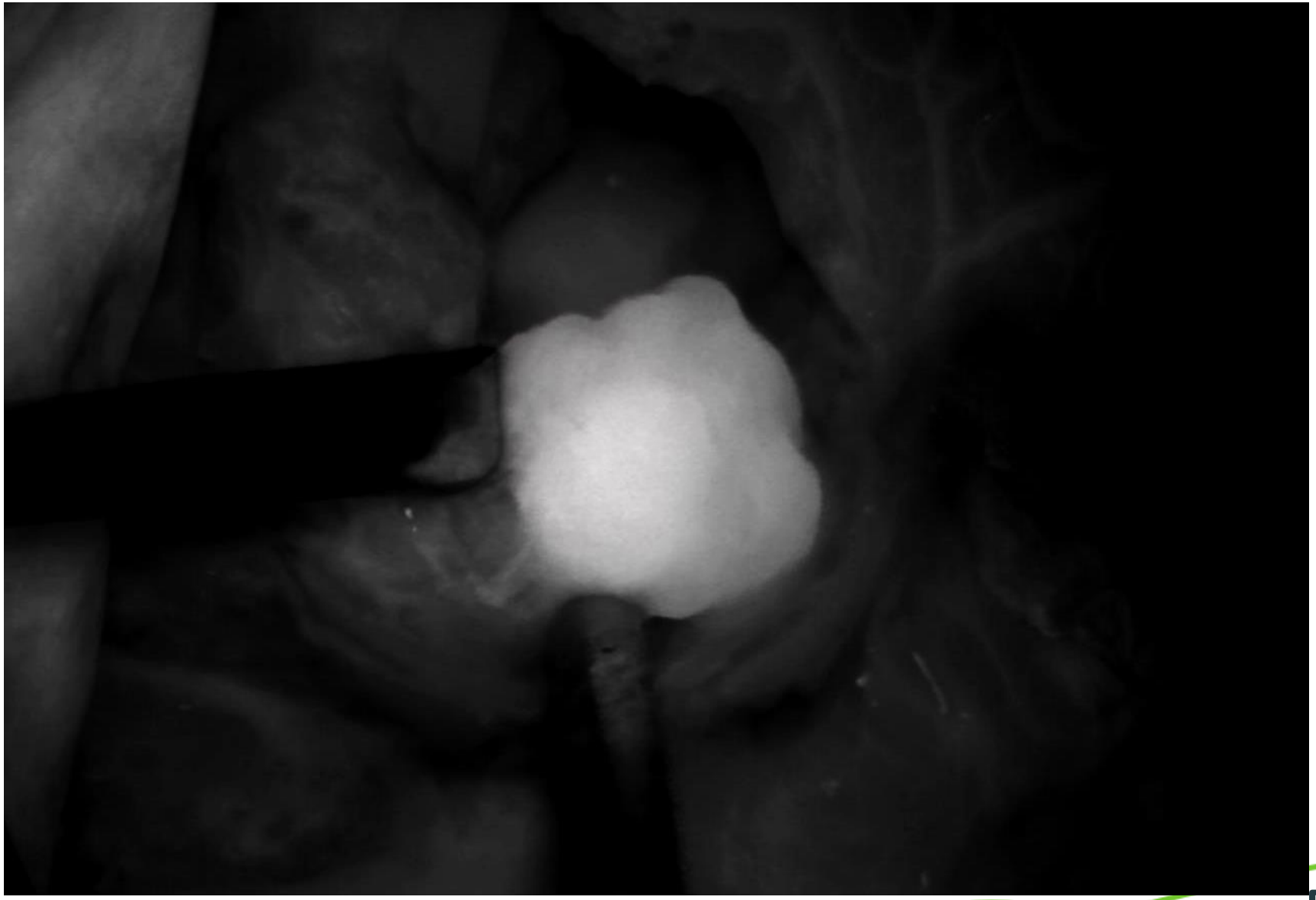
FluoGuide illuminates cancer



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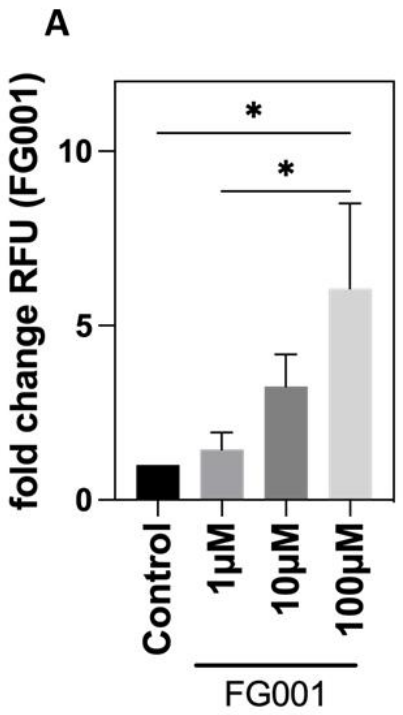
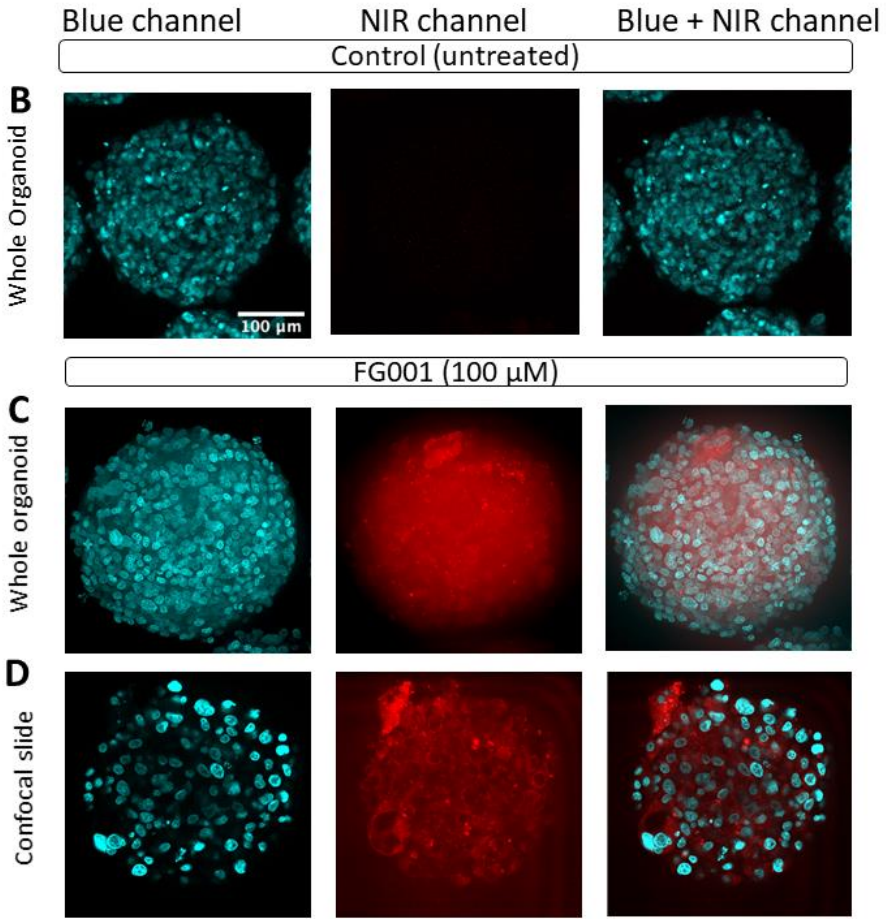
FG001 tested in blood-brain-barrier organoids model strongly suggest transcellular uptake





A) Bar chart plotting the fold change in FG001 signal within organoids compared to untreated controls as a measurement of degree of penetration.

B) Representative images of organoids (Z-projection of whole organoid). 4',6-diamidino-2-phenylindole (DAPI), visualizes nuclear DNA in both living and fixed cells. DAPI staining of healthy nuclei are seen in the blue channel while no signal is seen in the NIR channel.

C) Representative images of organoids (Z-projection of whole organoid) after incubation with FG001. DAPI staining of healthy nuclei are seen in the blue channel. Signal in the NIR-channel, from FG001 cellular uptake is seen in all cells.

D) Single slice representing 45µm within organoid. In NIR-channel FG001 signal overlap voids where cellular nuclei is (shown on Blue / DAPI channel). FG001 staining within all visible cells strongly suggesting uptake is transcellular and not paracellular.

Source: Presented as Poster-SNS2022: Juhl K. Performance and in vivo validation of an optical uPAR-targeted probe, ICG-Glu-Glu-AE105 (FG001), for surgical guidance in an orthotopic human xenograft glioblastoma model

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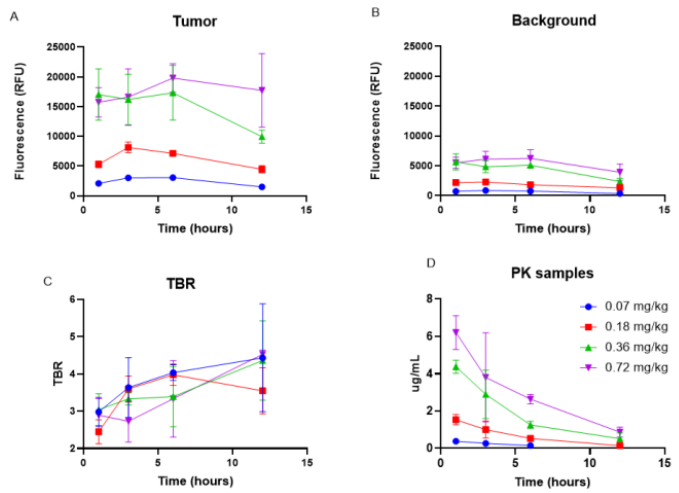
Preclinical GBM model demonstrates FG001 ability to illuminate malignancies

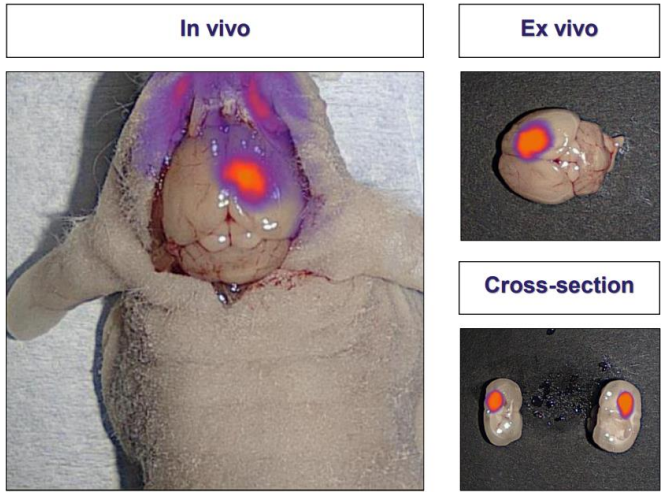
Orthotopic xenograft glioblastoma model

In vivo optical imaging shows TBR values above 2.5 with PK profiles showing dose-dependent exposure



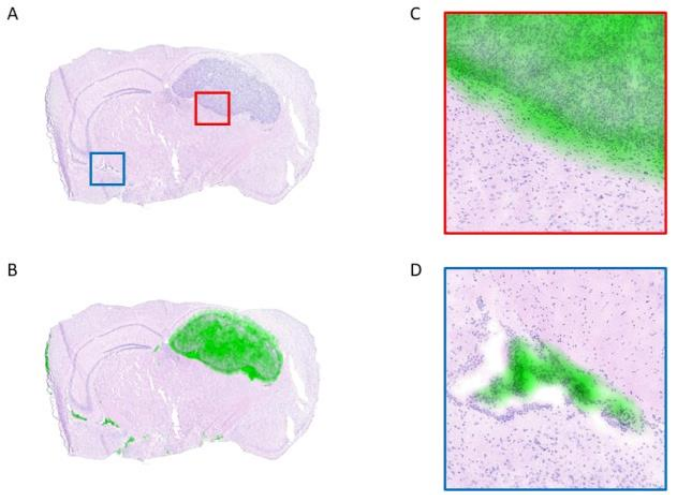
Significant TBR values at all tested doses

Images recorded by the EleVision IR camera demonstrates feasibility of intra-operational guidance



Feasibility in vivo

Fingerprint imaging shows precise delineation between tumor and healthy tissue



Clear differentiation

Source: Data on file

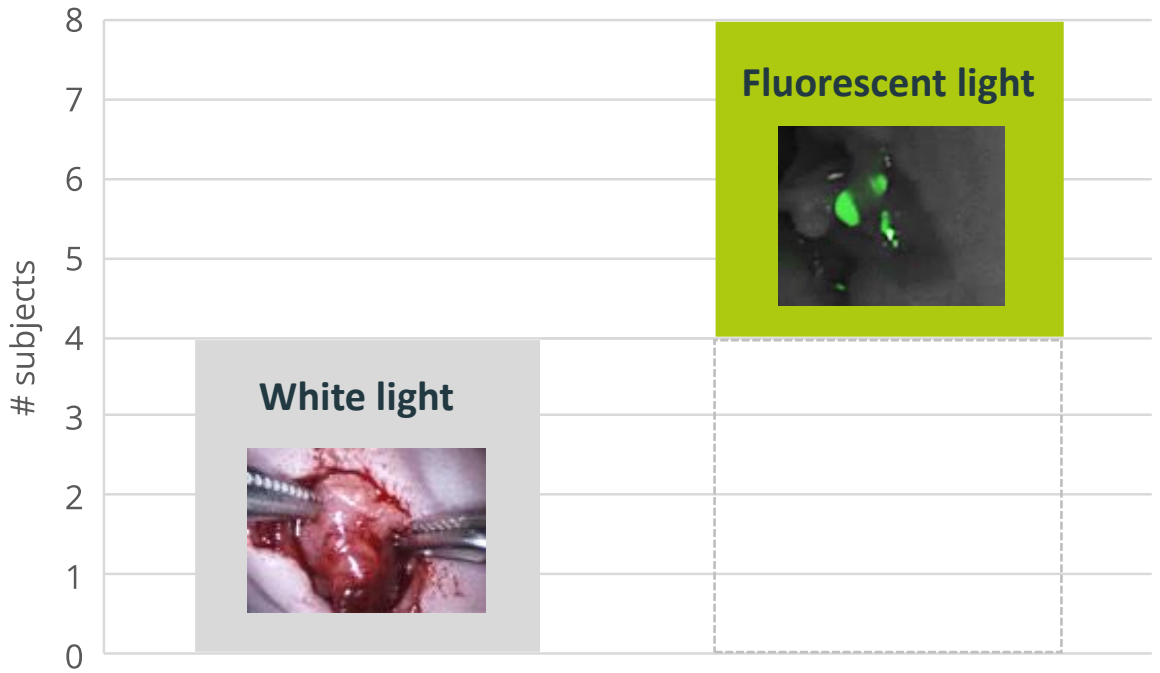
FluoGuide

Double the effect of surgery in mouse clinical trial

Pre-clinical testing of FG001, using a study design like what is required in humans (phase IIb/III)

- **Human cancer** (pancreatic)
- **Surgeon used same equipment as for humans (incl. robotic surgery with da Vinci)**
- **Used standard equipment available in hospital clinics**

Identified and removed local metastases in twice as many subjects as standard (white light) procedures



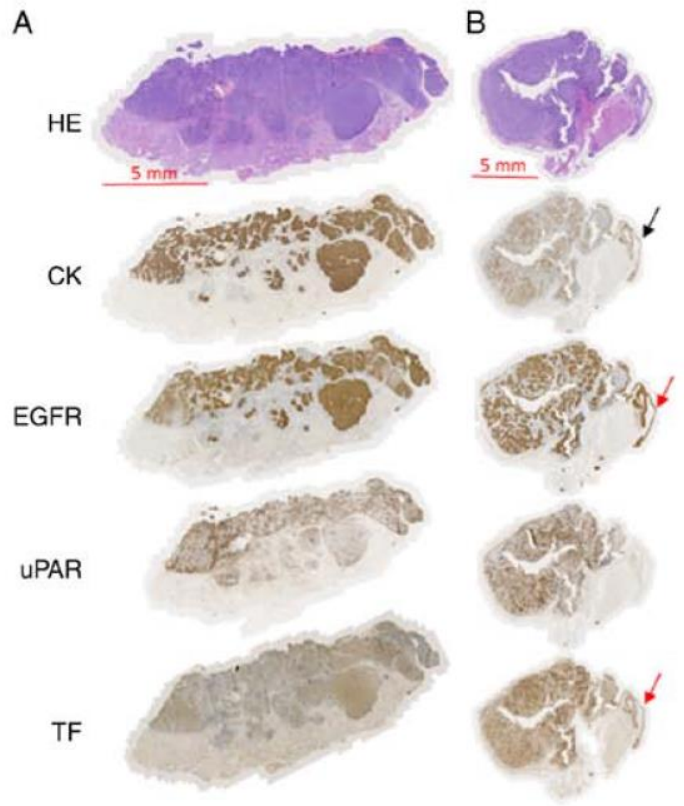
Subjects with metastases found with white and fluorescent light, respectively (n=8)

Source: Juhl K, Christensen A, Rubek N, Karnov KKS, von Buchwald C, Kjaer A. Improved surgical resection of metastatic pancreatic cancer using uPAR targeted *in vivo* fluorescent guidance: comparison with traditional white light surgery. Oncotarget. 2019 Oct 29;10(59):6308-6316. doi: 10.18632/oncotarget.27220. PMID: 31695839; PMCID: PMC6824874.

FluoGuide

Histopathology demonstrates uPAR specificity in Head & Neck cancer

uPAR shown to be a superior indicator of cancer presence compared to EGFR and TF



tumor A:

→ In tumor A, tumor-specific expression pattern is seen for all three targets, EGFR, uPAR and TF with an accurate demarcation of the cancerous tissue and absence of staining in the adjacent normal tissues when compared with the H&E and CK stainings.

tumor B:

→ Normal epithelium can be seen on the right side of the section (arrow), which stained strongly positive for Creatine Kinase (CK)

→ No cancer is observed in with Hematoxylin & Eosin staining (HE)

→ False positive staining obtained from both EGFR and TF stainings

→ No cancer staining (true negative) observed in the uPAR-stained tissue

Source: Christensen A, Grønhøj C, Jensen JS, Lelkaitis G, Kiss K, Juhl K, Charabi BW, Mortensen J, Kjær A, Von Buchwald C. Expression patterns of uPAR, TF and EGFR and their potential as targets for molecular imaging in oropharyngeal squamous cell carcinoma. Oncol Rep. 2022 Aug;48(2):147. doi: 10.3892/or.2022.8359. Epub 2022 Jul 1. PMID: 35775375; PMCID: PMC9263836.

FluoGuide

Strong patent protection until 2039

- Patent family WO2016041558
  - Protects FG001 (product protection)
  - Issued in Europe, the US, and Australia
  - Expires in 2034
  - Owned by FluoGuide
- Patent application family (PCT/EP2020/069991)
  - Protects FG002
  - The patent family is co-owned by FluoGuide and licensed from Copenhagen University Hospital and Rigshospitalet
  - Potential protection until 2039
- Patent application family (PCT/EP2020/070014)
  - Related to uses of several different product targeting uPAR
  - Owned by FluoGuide
  - Potential protection until 2039
- Additional patent filings are anticipated to further protect the uPAR technology platform improving surgery

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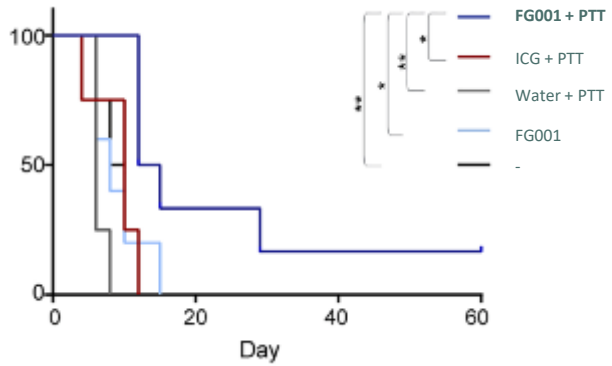
FluoGuide awarded prestigious grant

Tumor survival in mice



Tumor survival after FG001 based PTT
FG001 + PTT (n = 6), ICG + PTT (n = 4), Saline + PTT (n = 4), FG001 (n = 5) and Control (n = 4) groups respectively

Survival curves for the different groups. When comparing survival curves between the FG001 + PTT group and the different control groups, *denotes p value < 0.05 and **denotes p value < 0.01.

Grant awarded to FluoGuide and four academic partners

- The grant aims to support the research and development of the optimal molecule for photothermal therapy while using **FG001** as a model molecule
- The grant valued at **DKK 49.1 million** (approx. EUR 6.6 million or SEK 75.6 million)
- Photothermal therapy could become a new pillar in the treatment of cancer and has the potential to significantly contribute to the **long-term growth of FluoGuide**.

Source: Simón et al, Oncotarget, 2021 Jul 6;12(14):1366-1376

FluoGuide

Traded on Nasdaq First North Growth Market Stockholm - Ticker: FLUO

Shareholders	Number of shares	Percentage ownership
Flagged		
Life Science ApS [1)]	2,126,107	18.0%
Wexotec ApS [2)]	1,488,610	12.6%
Linc AB	819,630	6.9%
Arbejdernes Landsbank A/S	797,973	6.8%
Management & Board of Directors		
Management and BoD together owns 35.5% of the total amount of outstanding shares		
Grethe Nørskov Rasmussen [3)]	373,185	3.2%
Pme Holding ApS [4)]	115,669	1.0%
Micaela Sjökvist [5)]	62,163	0.5%
Shomit Ghose [5)]	21,143	0.2%
nuso ApS [6)]	1,431	0.0%
Mats Thorén [5)]	741	0.0%
Dorthe Grønnegaard Mejer [3)]	724	0.0%
Other shareholders		
Other	6,007,124	50.8%
Total	**11,814,500**	**100%**

1) Life Science IvS is a wholly owned company by Board Member, CSO and CMO Andreas Kjaer
2) Wexotec ApS is a wholly owned company by CEO Morten Albrechtsen
3) Grethe Nørskov Rasmussen and Dorthe Grønnegaard Mejer is part of Management
4) Pme Holding ApS is a wholly owned company by Director of the Board Peter Mørch Eriksen
5) Member of the Board of Directors
6) nuso ApS is a wholly owned company by CFO Ole Larsen

Research coverage

- ✓ **ABG Sundal Collier**
- ✓ **SEB** (commissioned)
- ✓ **Redeye** (commissioned)
- ✓ **Økonomisk Ugebrev**

***Management and founders hold approximately 35% of total shares**

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