

FluoGuide

Precision surgery improving outcome for cancer patients

HC Andersen Investor Seminar

Morten Albrechtsen, CEO
16 January 2025



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FluoGuide at a glance

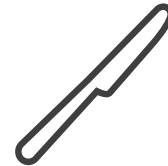
2018 Year Founded	CPH, DK Headquarter & location	FLUO Listed at First North Stockholm
Oncology surgery Large unmet medical need	FG001 Improving outcome for cancer patients	≈ 20 millions Patients per year
Intuitive Surgical Non-exclusive partnership	Phase II Stage of most advanced clinical asset	3 Positive phase II results in different cancer types



A huge need for precision surgery

≈20 million
new patients

are diagnosed with
cancer every year



**Surgery is the
primary treatment**

when the goal is to cure.
Surgery, radiation- and/or
chemotherapies are the options

≈12 million
cancer patients

each year undergo surgery with
the purpose of cure



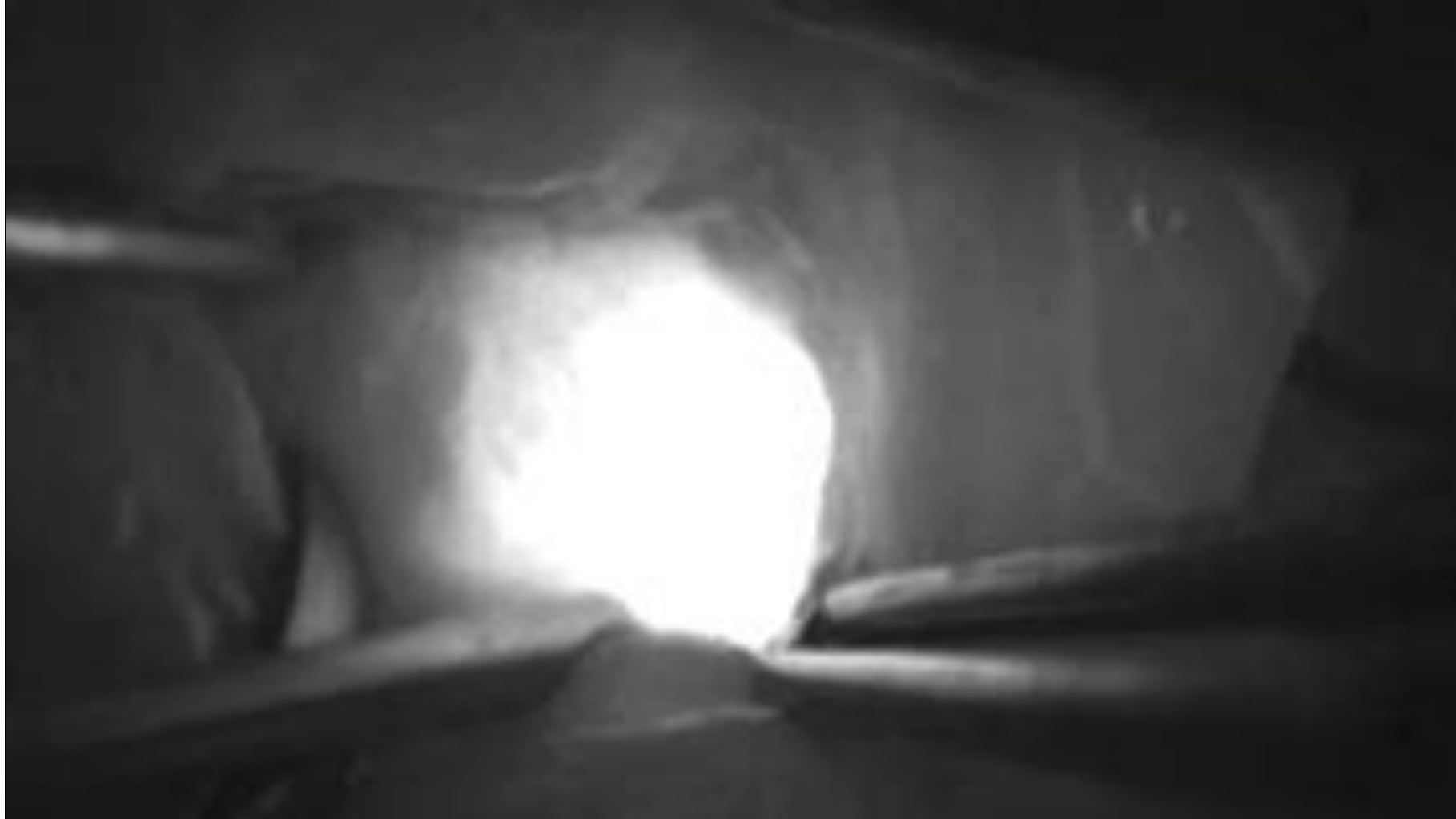
 ≈ 90%

 ≈ 40%

50% of the patients

experience local recurrence of
cancer after the surgery

FluoGuide illuminates cancer



Increasing demand for precision and image guidance in surgery

Market drivers



Growing aging population

The world's population aged 65 or older is projected to more than double by 2050



Surgeon shortage

The world faces a shortage of surgeons



Need for new surgical technologies

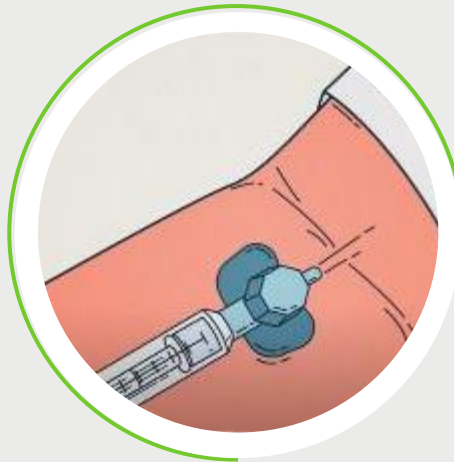
Rising demand, lack of skilled surgeons and increased complexity of surgery, lead to an increased need for new technologies

FluoGuide-powered precision surgery: Proprietary uPAR probe

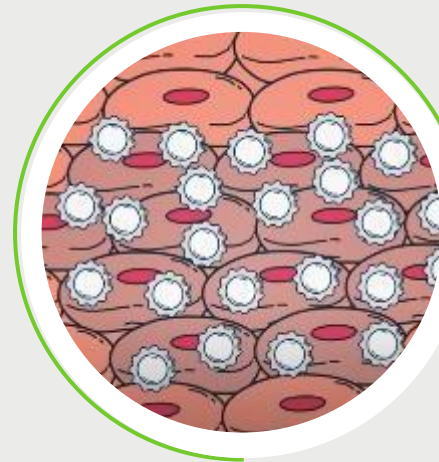
**Fluorescent Probe
FG001**



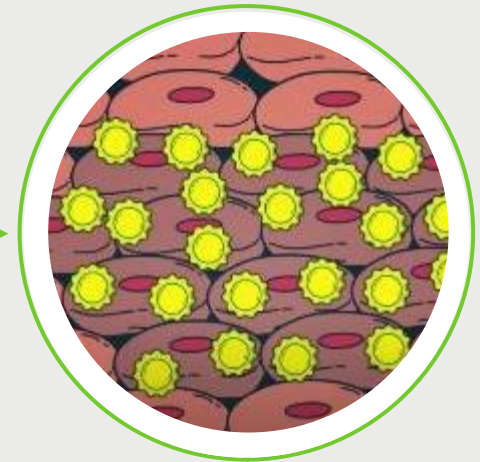
**Injected prior
to surgery**



**Binding to
cancer**



**Guiding during
surgery**

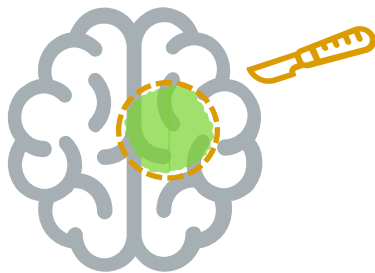


← 4 hours – 2 days →

Precision improves outcome of surgical treatment

Precision surgery

Enhance precision surgery through illumination of cancer cells and guiding the surgeon

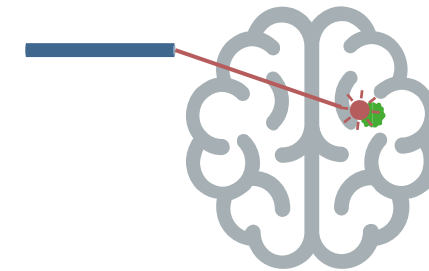


FG001

uPAR-binding
fluorescent molecule

Precision treatment

Property as photosensitizer can remove cancer cells while sparing surrounding tissue



FG001 has a high likelihood of success – positive data in 3 cancer types

Overview of clinical development of FG001

- ✓ **Tested in three cancer indications:** Aggressive brain cancer, lung cancer, and head and neck cancer
- ✓ **Successful clinical trials:** All three phase II clinical trials (one in each indication) has demonstrated that FG001 is effective
- ✓ **Good patient tolerance:** More than 91 patients have received FG001, showing it to be well-tolerated
- ✓ **Compatibility with existing equipment:**
 - FG001 dosing is not limited by toxicity
 - Tested with multiple different types of equipment
 - FG001's effectiveness could be further optimized through partnering collaborations with equipment manufacturers
- ✓ **Pre-clinical studies on treatment effect (as photosensitizer):** Demonstrated therapeutic effect when combined with laser in pre-clinical models

Pipeline with low risk and long-term patent protection

	INDICATION	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
FG001					
	Brain cancer High-grade glioma				
	Head and neck cancer Squamous cell carcinoma				
	Lung cancer Non-small cell				
	Photosensitizer therapy Brain cancer				

 FG001 patent protected until 2035 (granted in Europe, USA, Canada and Australia)

 Patent for several products targeting uPAR until 2040 (pending applications in Europe and USA)

 Additional patent applications are pending offering additional protection

The market on brain tumor - more precise surgery is needed

The surgeon's dilemma



The cavity after removal of obvious cancerous tissue

- Removing too much, risking to **destroy critical functions** in the patient
- Leaving too much and **risking recurrence**

Need

- Many patients experience cancer recurrence
- The brain is a vital organ
- 5-ALA is approved in <10% of brain cancer indications

Market characteristics

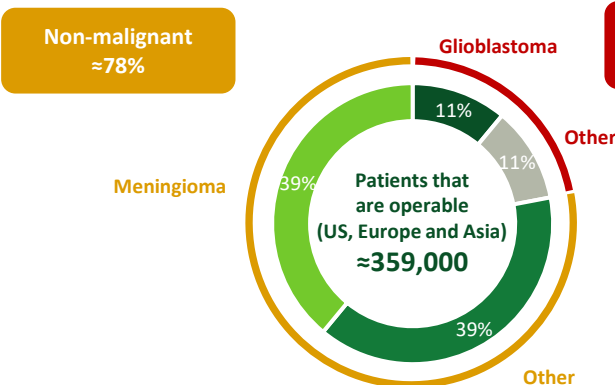
- Duopoly within surgical equipment
- The market is well-penetrated with equipment
- Limited innovation within equipment

Client base

- Focused group with knowledge about the fluorescence-guided surgery (FGS)

The market in numbers

Primary brain-tumors



Secondary brain-tumors

Brain-metastases typically originate from lung (60%) or breasts (11%)



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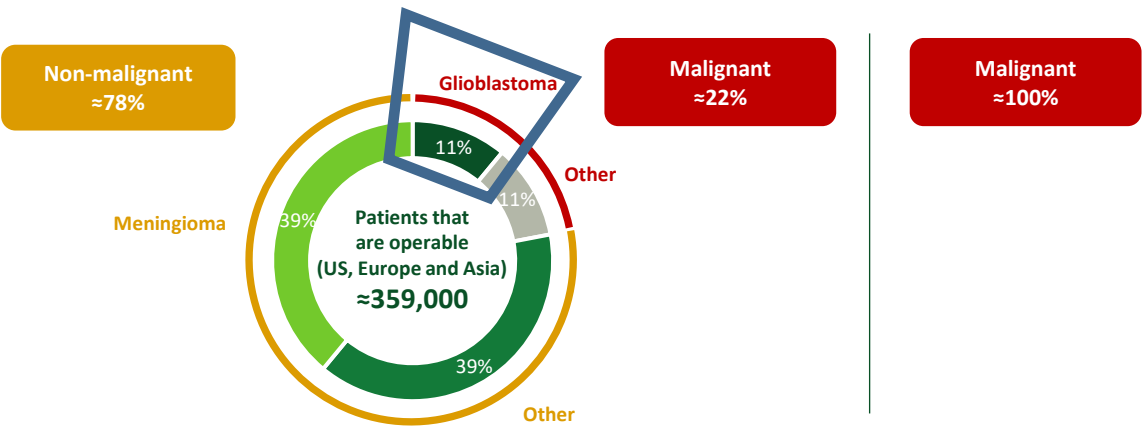
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Aggressive brain cancer – positive results

	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)

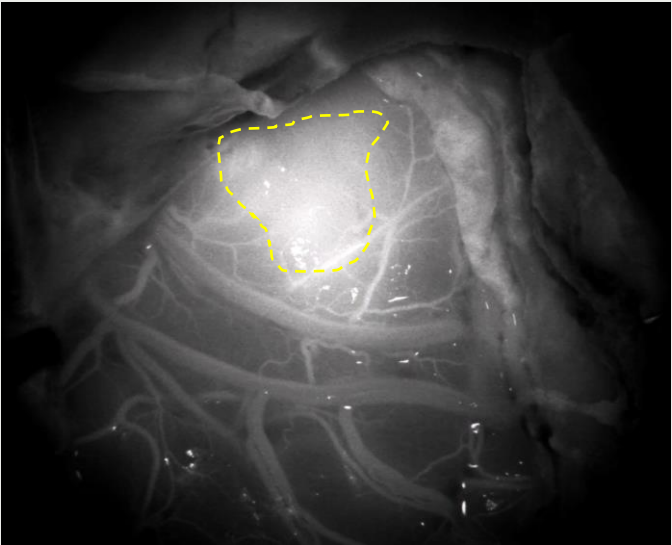
- 1

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

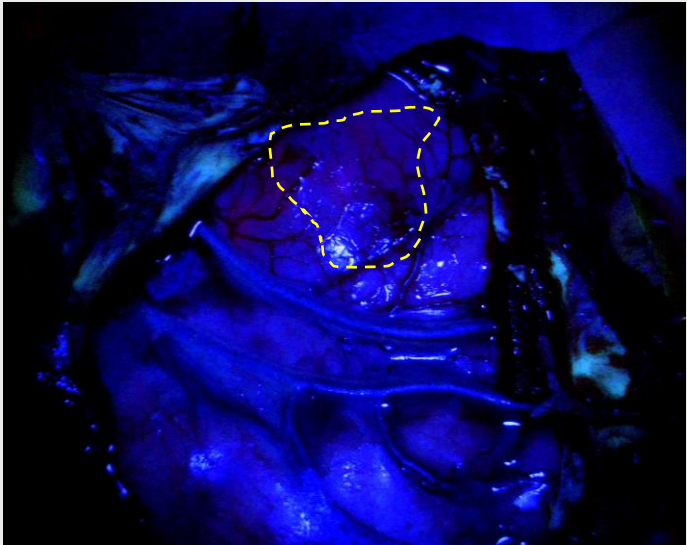
FG001 was safe and well tolerated in all patients with 2 related AEs (grade 1)
The result for 5-ALA was 10 related AEs (8 grade 1 and 2 grade 2).
- 3

FG001 visualize tumor on dura prior to incision in 4/12 patients (deeper visualization).
The result for 5-ALA was 0/12.

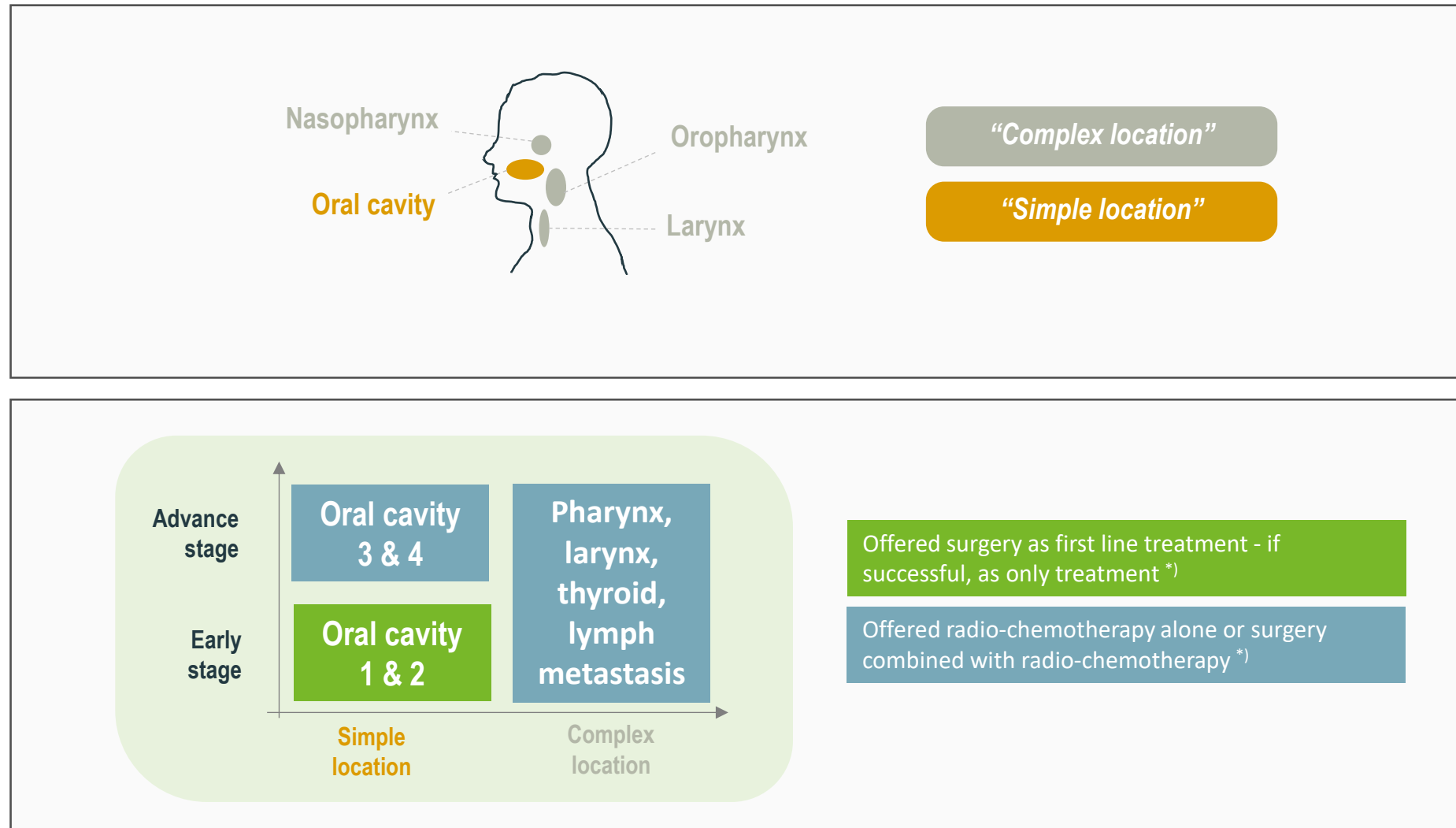
FG001



5-ALA



Treatment of head and neck cancer depend on location and stage



Head and neck cancer (CT-003): Positive results

	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 (FG001-CT-003)

1

FG001 demonstrated a sensitivity on 100% Relevant contrast - TBR*) - in all 16 patients on >2.00 and (2.99 in average)

2

FG001 was safe and well tolerated in all patients

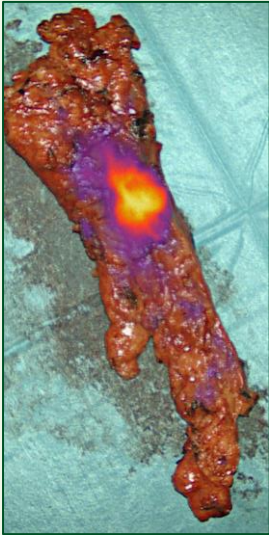
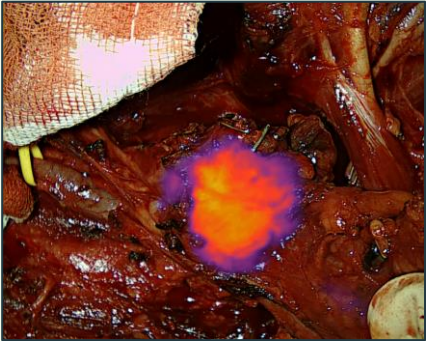
3

FG001 revealed several demonstrated fulfilment of several unmet medical needs in head & neck cancer surgery, eg.: Lymph node cancer detection and cancer margins assessment

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



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



15

Sources: Company information; FG001-CT-001, data on file.
*)TBR (Tumor to background ratio)

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Cancer surgery offers multiple potential partnerships

Surgical equipment		Indications and reason for use	Example of vendors
Microscope		Brain surgery Visualization of small structures	  
Open field camera		Multiple, eg. head & neck, brain Visualization of superficial cancers	  
Endoscope		Multiple, eg. head & neck, lung, colorectal Flexible for visualization and operation inside the body	     
Robot		Multiple, eg. head & neck, lung Allows multiple arms and remote control	  
Back table histology		Multiple, eg. head & neck Allows multiple arms and remote control	 

Business model

Surgical equipment		Indications	Sales model/sales approach
Microscope		Brain cancer	• Directly to hospitals • Through device manufactures. Equipment well penetrated • Partly established market
Open field camera		Head & neck cancer	
Endoscope			
Robot			• Directly to hospitals • Through device manufactures. FG001 facilitates new equipment sale • Less established market
Back table histology			

Partnership with Intuitive Surgical

A non-exclusive, non-cash agreement with the aim to develop FG001 for tumour imaging and surgical margin assessment in H&N cancer, using Intuitive's equipment



INTUITIVE
SURGICAL®

Listed on Nasdaq with a market cap of approx. USD 135 billion
(the world's 103rd largest listed company by market cap)

- + Initial validation of FluoGuide's approach
- + Paving the way for FluoGuide's 'multiple indication/application partnerships strategy'
- + Aim at integration/optimization to Intuitive's equipment
- + Potential to integrate FluoGuide's product into Intuitive's product offering
- + Important milestone in clinical development as well as commercialization strategy implementation
- + Low risk that partners will exploit the opportunity and narrow the possibilities for future agreements

Effective organization with strong experience in developing and commercializing health care products



Management team
of which all have previously taken a product from clinical trials to commercialisation

Board of Directors



>90% of FluoGuide's operational costs relates to R&D¹



Source: Company information, Note: (1) Annual report for the financial year of 2023

Listed on Nasdaq First North Growth Market Stockholm

Owner distribution (approx. figures)



Analyst coverage

Ticker: **FLUO**

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

2025 Timelines and milestones

2025			
Q1	Q2	Q3	Q4
• Enrolment of first patient in phase II clinical trial in head and neck cancer (CT-005)		• Submit application for clinical trial in High Grade Glioma (HGG)	
• Regulatory evaluation and consultation with FDA to confirm the design of registration trial for FG001 as an imaging agent in guiding aggressive brain cancer • Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma • Complete optimization of the combined use of FG001 and the laser system in pre-clinical models as a photosensitizer therapy in brain cancer		• Interim data from first 15 patients in phase II clinical trial in head and neck cancer (CT-005) • Submit for regulatory feedback for registration trial in head and neck cancer	
• 1-2 additional partnerships			

Brain • Head and neck • Commercial

Timelines and milestones

2025			
Q1	Q2	Q3	Q4
Enrolment of first patient in phase II clinical trial in head and neck cancer (CT-005)		Submit application for clinical trial in High Grade Glioma (HGG)	
- Regulatory evaluation and consultation with FDA to confirm the design of registration trial for FG001 as an imaging agent in guiding aggressive brain cancer - Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma - Complete optimization of the combined use of FG001 and the laser system in pre-clinical models as a photosensitizer therapy in brain cancer		- Interim data from first 15 patients in phase II clinical trial in head and neck cancer (CT-005) - Submit for regulatory feedback for registration trial in head and neck cancer	
1-2 additional partnerships			

Brain • Head and neck • Commercial

Long term		
- Approval of FG001 in USA - Expand FG001 indication to target larger part of the brain tumor market where currently no imaging agents are approved - Expand FG001 as a photosensitizer to address another large unmet medical need and broaden market potential	Facilitate commercialization with support from partner(s)	- First approval of FG001 in head and neck - Expand FG001 indication to large market for head and neck cancer where currently no imaging agents are approved

2025 Outlook

	Ongoing tasks		2025 Milestones	Long term objectives
Brain	FG001 - guiding surgery of High-Grade Glioma (HGG)	Continue development and regulatory path towards market approval	H1: Regulatory evaluation and consultation with FDA to confirm the design of registration trial for FG001 as an imaging agent in guiding aggressive brain cancer H2: Submit application for clinical trial	Approval of FG001 in USA
	FG001 - guiding surgery of additional brain tumors (e.g. Meningioma)	Evaluate FG001 for additional brain indications (expand market potential by up to 20x compared to HGG)	H1: Preliminary data from an investigator-initiated trial involving 20 patients with meningioma and low-grade glioma	Expand FG001 indication to target larger part of the brain tumor market where currently no imaging agents are approved
	FG001 - photosensitizer therapy for brain cancer	Evaluate and implement photosensitizer therapy into brain cancer development (expand potential in value by up to 20x compared to guiding surgery)	H1: Complete optimization of the combined use of FG001 and the laser system in pre-clinical models	Expand FG001 as a photosensitizer to address another large unmet medical need and broaden market potential
Head and neck	FG001 - guiding surgery of head and neck cancer	Continue development of head and neck clinical program towards market approval	Q1: Enrolment of first patient (CT-005) H2: Interim data from first 15 patients (CT-005) H2: Submit for regulatory feedback for registration trial	First approval of FG001 in head and neck Expand FG001 indication to large market for head and neck cancer where currently no imaging agents are approved
Partnering	Preparing additional partnerships for FG001	Advancing the tasks defined in the partnership with Intuitive Surgical	H1: 1-2 additional partnerships	Facilitate commercialization with support from partner(s)

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