

FluoGuide

Precision surgery improving outcome for cancer patients

Life Science Investor Conference, 28 February 2024

Morten Albrechtsen, CEO



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A need for more effective cancer surgery

Cancer remains to the second most common cause of death globally

18.1 million
new patients

are diagnosed with cancer every year

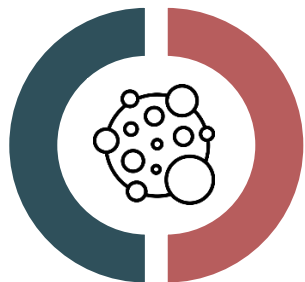


Surgery is the primary treatment option for patients with localized cancer

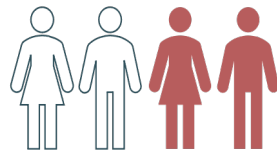


80% of cancer patients
will undergo surgery

Local recurrence of cancer following surgery is frequent



50% of patients
have local recurrence



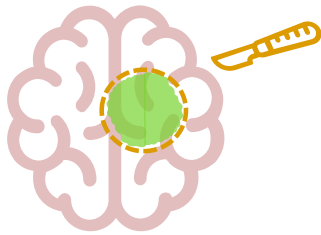
Visualization and palpation
is largely the standard

in surgical localization, which is prone to miss cancerous cells and remove too much healthy tissue

FluoGuide - Precision improves outcome of surgical treatment

Guided surgery

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

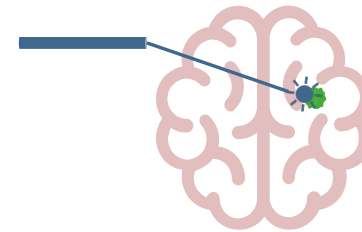


- PoC in three clinical indications: Aggressive brain, head & neck and lung cancer
- Well tolerated in all patients
- Equipment agnostic

FG001
from our unique
**uPAR-targeting
technology**
with
dual benefit

Photothermal treatment

Photothermal properties offer opportunity to remove hard-to-reach cancer cells



- PoC in pre-clinical model
- Photothermal therapy grant on €6.6m

FluoGuide is a pioneer in surgical treatment of cancer

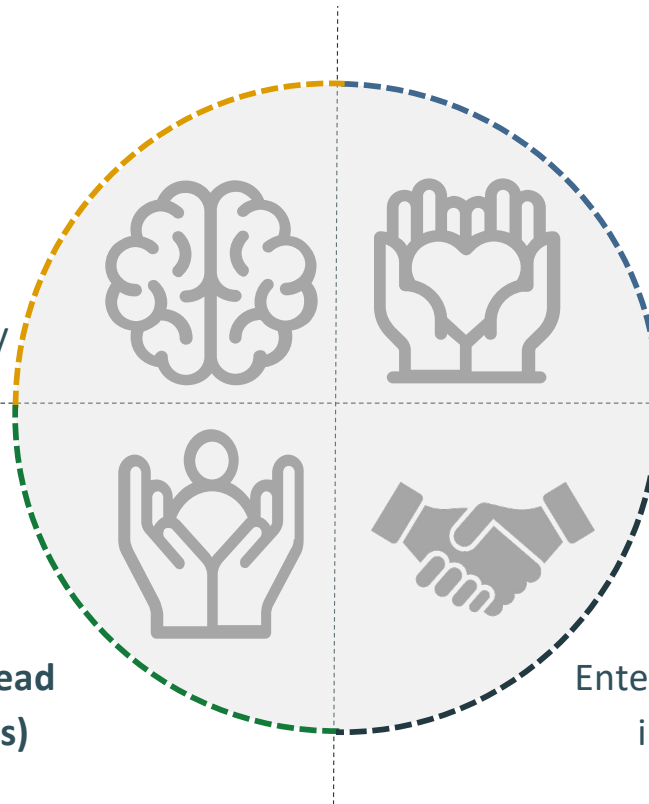
Targets for 2024 and beyond:

Advancing FG001 toward market

Proceed with **regulatory review** to confirm **trial design for FG001** as imaging agent for brain cancer surgery

Expanding the number of patients

Initiating a **phase II trial** of FG001 in **head & neck cancer**, with **benefit endpoint(s)**



Enhancing the benefit

Evaluate and implement **photothermal therapy** into brain cancer development

Prepare commercialization

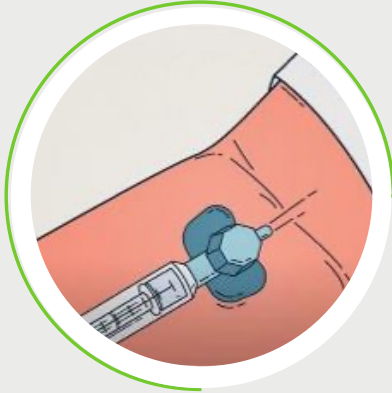
Enter into **partnership agreement(s)** for FG001, in accordance with our partnership strategy

FluoGuide-powered precision surgery: Proprietary uPAR probe

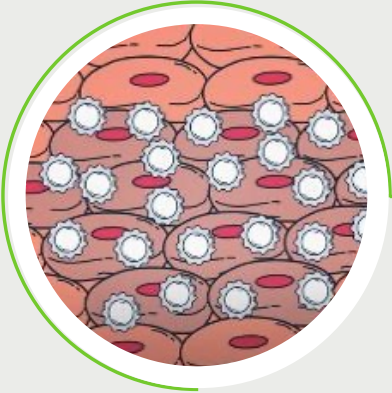
**Fluorescent Probe
FG001**



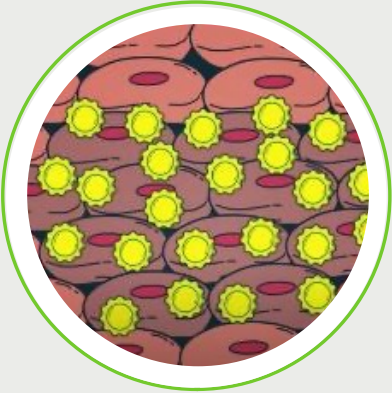
**Injected prior
to surgery**



**Binding to
cancer**



**Guiding during
surgery**



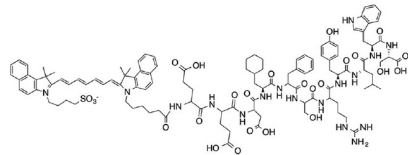
FG001 – a uPAR targeted imaging agent

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*)



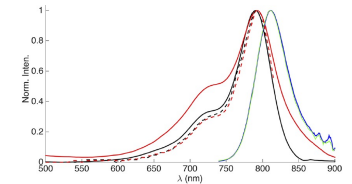
ICG-Glu¹-Glu²-Asp³-Cha⁴-Phe⁵-(D)ser⁶-(D)arg⁷-Tyr⁸-Leu⁹-Trp¹⁰-Ser¹¹

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

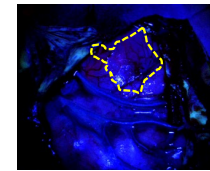
3. FG001 same spectral characteristics as ICG (device agnostic)

— Absorption ICG
 — Absorption FG001
 - - - Excitation ICG
 - - - Excitation FG001
 — Emission ICG
 — Emission FG001

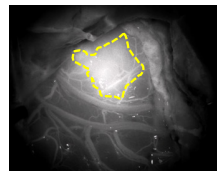


4. Near-infrared light leads to deeper tissue visibility

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



2. generation (FG001)
1-2 cm



FluoGuide illuminates cancer



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

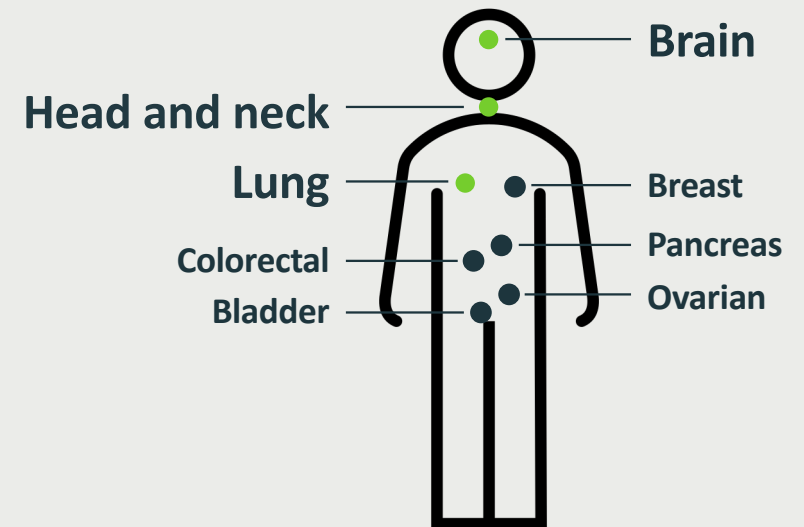


Expression is **proportional to cancer aggressiveness**



Recognised target supported by a large scientific body¹

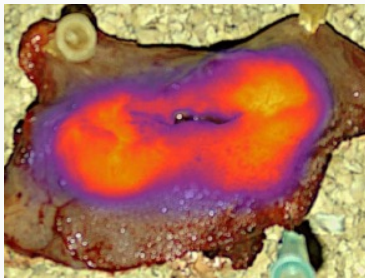
>80% of solid cancers express uPAR



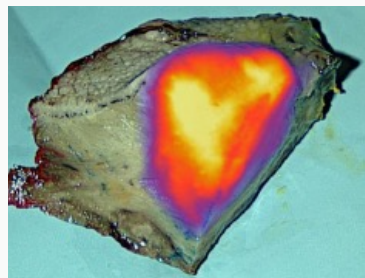
uPAR expression and FG001 binding to cancer

Macro imaging

Fresh tissue

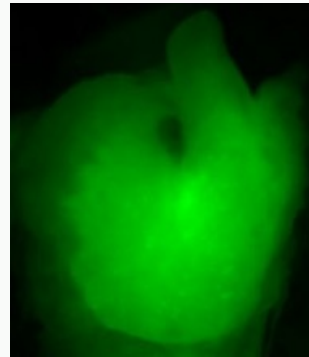


Formalin fixed tissue

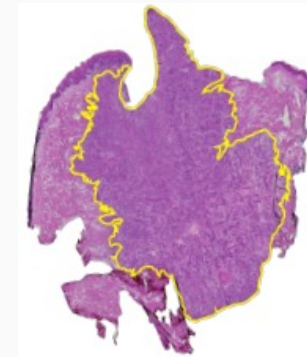


Micro imaging

FG001



H&E

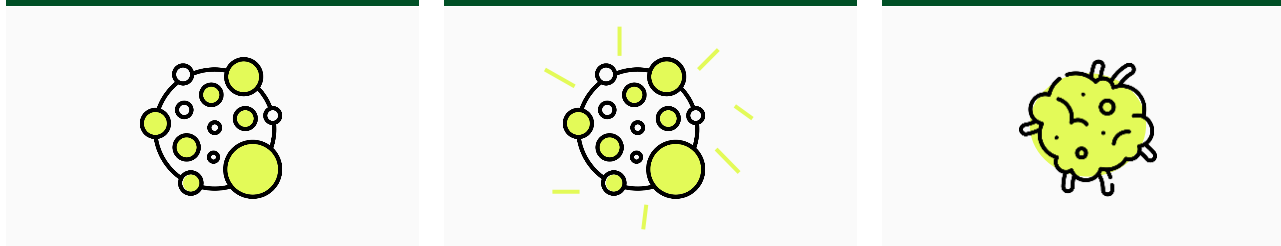



uPAR



Therapeutic applications with uPAR targeted photothermal treatment (FG001)

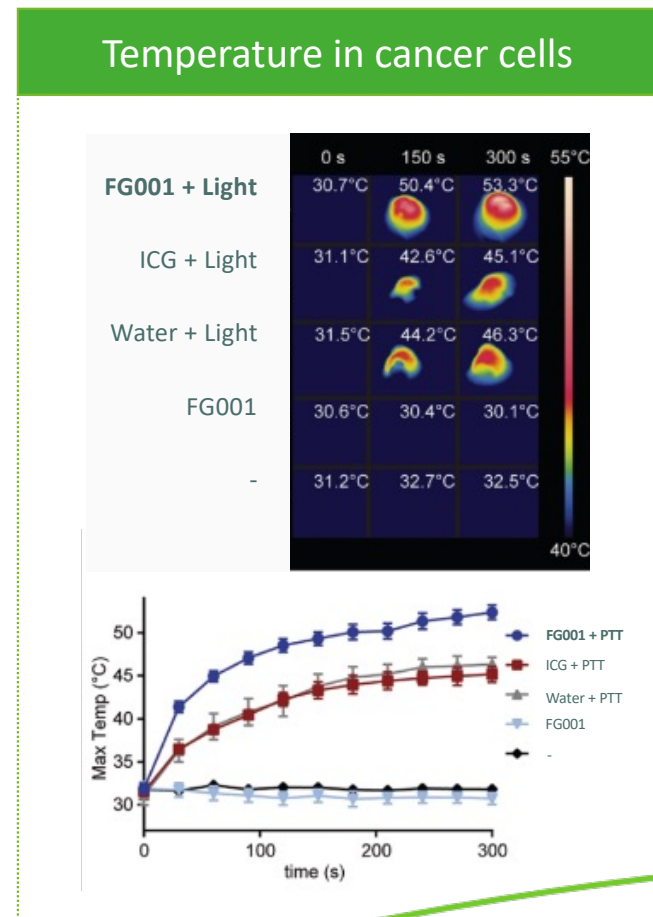
- 1 | FG001 binds to uPAR
- 2 | FG001 is excited with light of specific wavelength
- 3 | FG001 releases energy in the form of light emission and heat




 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



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



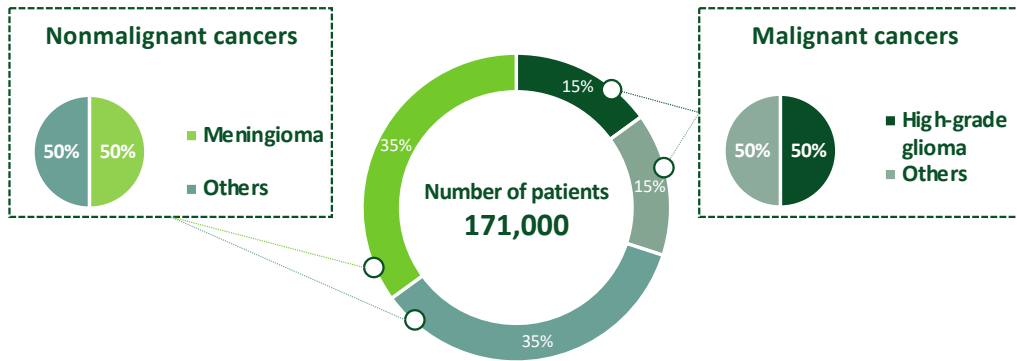
Detect and remove additional cancer



Spare critical functions

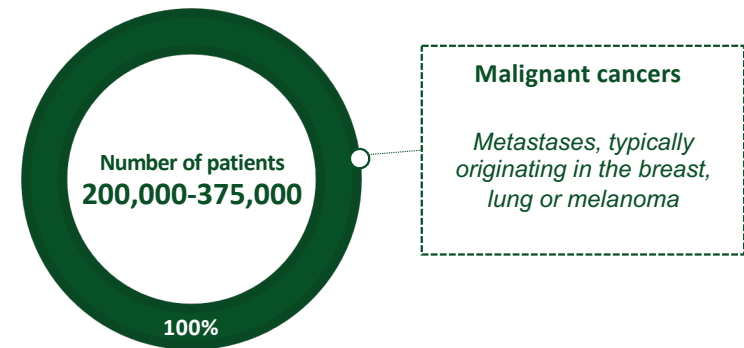
Precise tumor resection improves patient outcomes in brain cancers

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

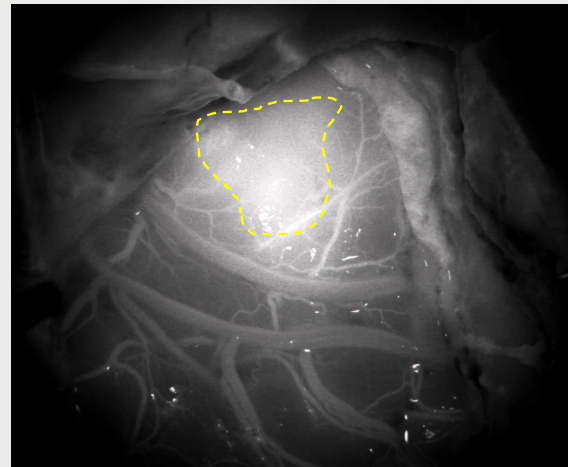
Aggressive brain cancer – positive results

	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

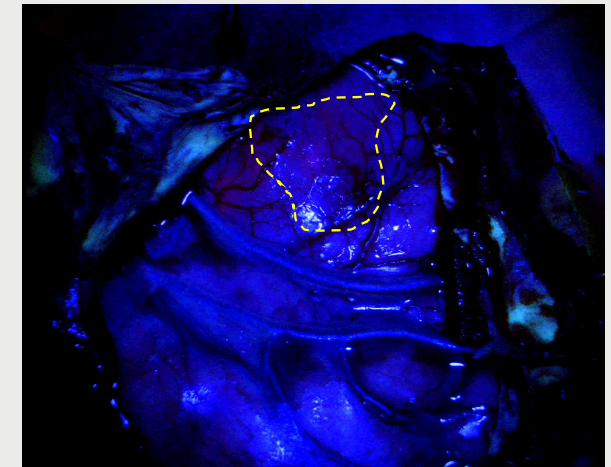
Trial results (FG001-CT-001)

- 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.

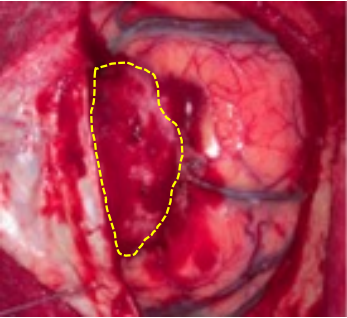
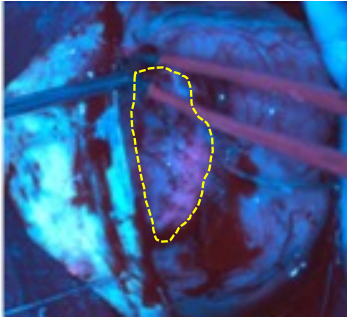
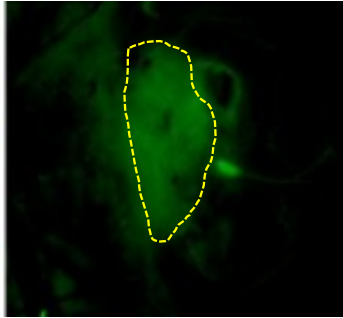

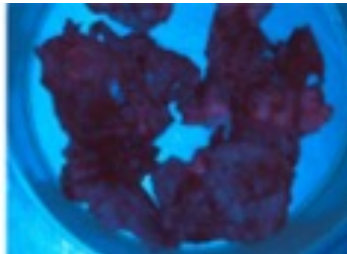
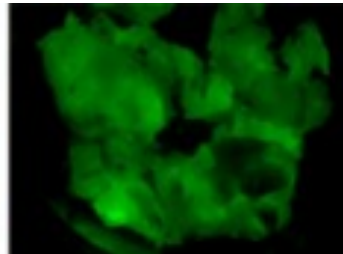
FG001



5-ALA



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

Plans for FG001 in brain cancer 2024

1 | Advance FG001 toward registration in brain cancer

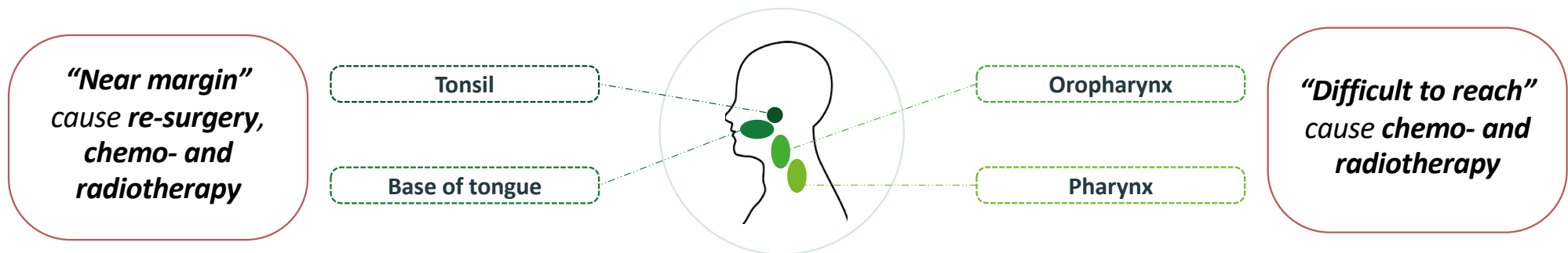
- Confirm design of registration trials as an imaging agent
- Assessing the potential of photothermal therapy (PTT) in aggressive brain cancer (HGG)
- Expand the label of FG001 expanding the commercial potential
- Expanding support for reimbursement

2 | Regulatory evaluation to confirm design of registration trials as an imaging agent

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

4 | Expand documentation for safety and efficacy

The challenges in head and neck cancer surgery



The solution: More precise surgery

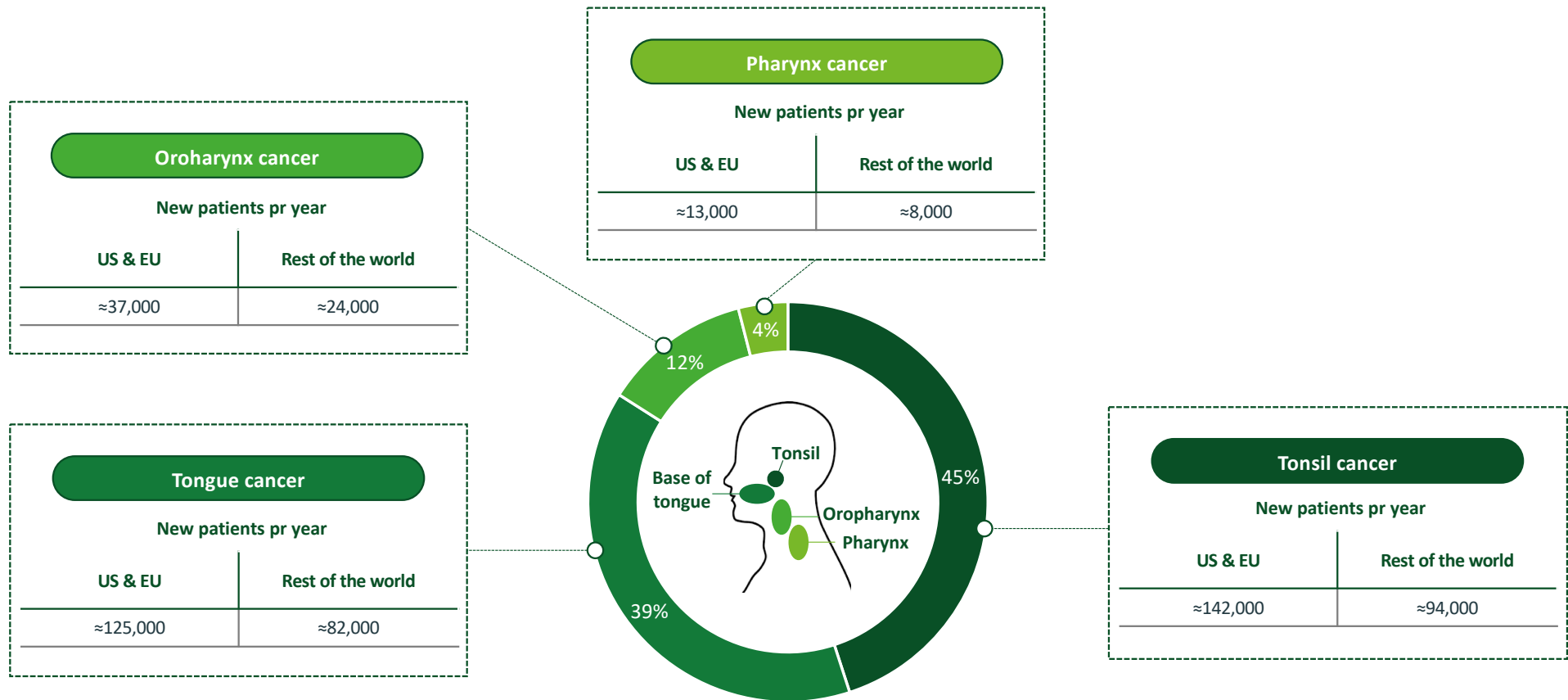


Check for margins during surgery



Enable surgical removal by minimal invasive surgery

Precise tumor resection enables close margins & reachability



Head and neck – positive result

	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.



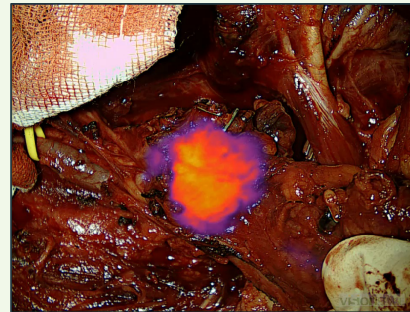
Head and neck – positive result

	Phase II
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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

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

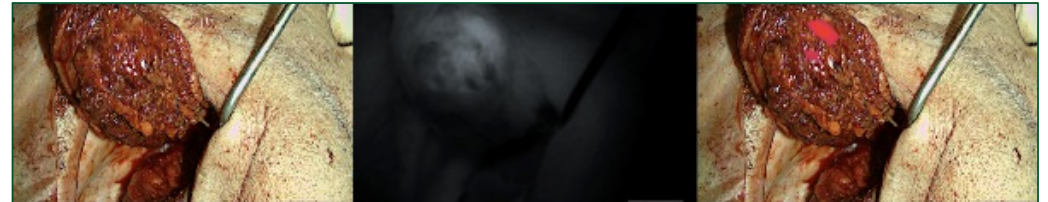


A range of opportunities for the patients and hospitals

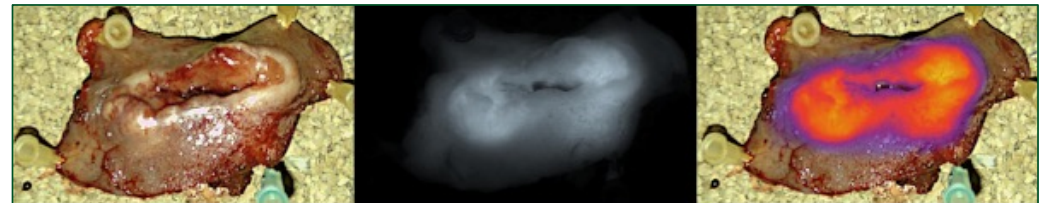
Potential clinical benefits

- **Pre-operative planning of surgery:**
 - Spare hospital time,
 - Spare tongue 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



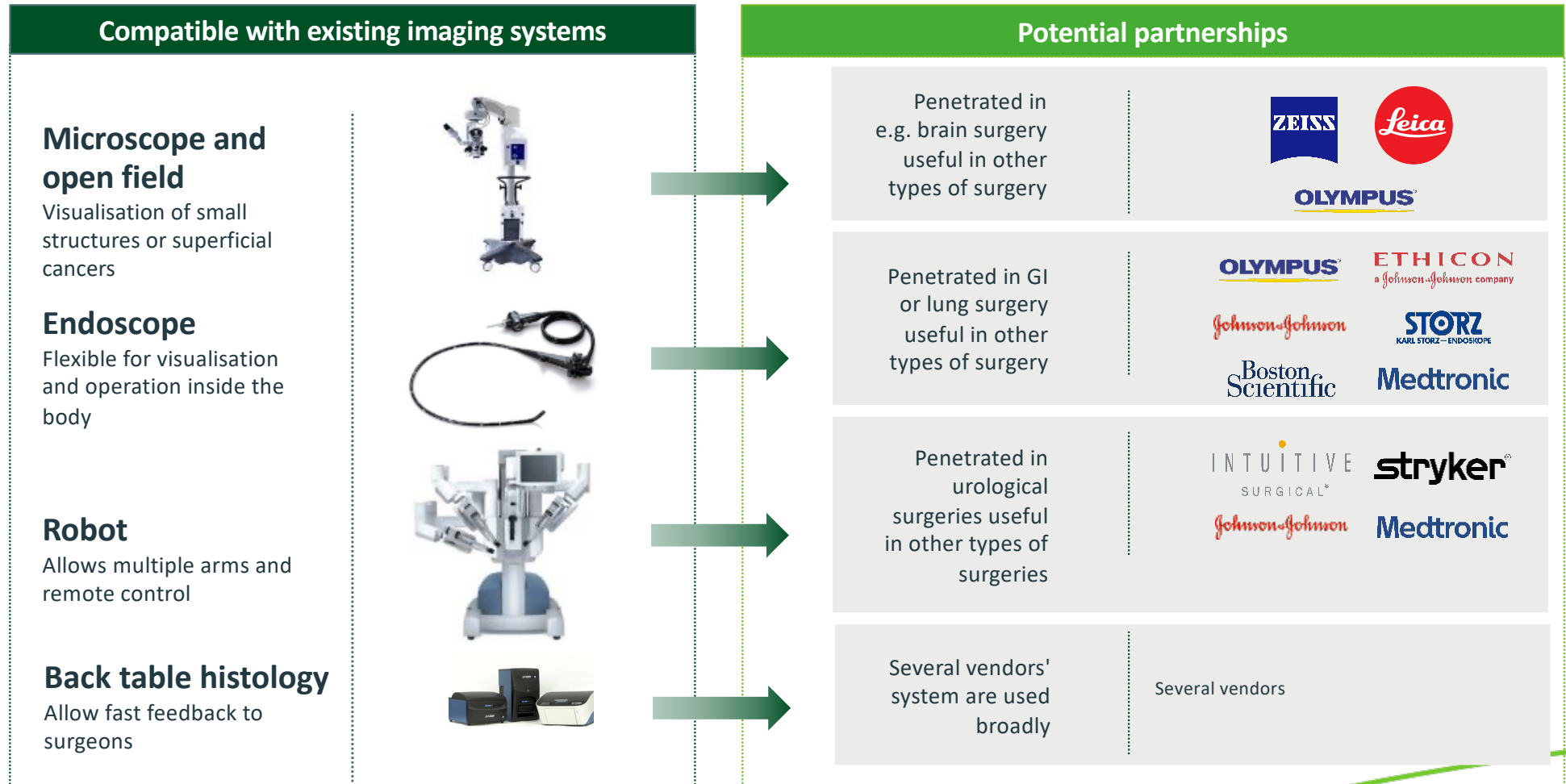
1) Back-table image of the tumor



2) Tumor metastasis during surgery



Head and neck cancer surgery offers multiple potential partnerships



Plans for FG001 in head & neck cancer in 2024

1 | Advance FG001 toward registration in head & neck cancer

- Initiate phase II trial with benefit endpoint(s)
- 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 evaluation

3 | Expanding commercial opportunities

4 | Expanding partnership opportunities

Upcoming clinical milestones and news flow



Archived until end 2023



Anticipated in 2024



Anticipated in 2025

Clinical development

- ✓ Demonstrated FG001 to be safe and well tolerated
- ✓ Proof of concept in aggressive brain, head and neck (OPSCC), and lung (NSCLC) cancer
- ✓ Clarification on clinical end-points for registration studies in aggressive brain cancer
- ✓ Orphan drug designation on FG001 in US for aggressive brain cancer
- ✓ Photothermal therapy grant on €6.6m

Clinical development

- Confirm design of registration trials as an imaging agent
- Phase II trial in head & neck cancer
- Evaluation of photothermal therapy in aggressive brain cancer

Clinical development

- Initiation of FG001 registration trial for aggressive brain cancer as imaging agent
- Results from phase II trial in head & neck
- Clinical trial result on photothermal therapy for aggressive brain cancer

Business development & strategy

- ✓ IPO in 2019
- ✓ Listed on Nasdaq First North Stockholm

Business development & strategy

- Partner collaboration(s)

Business development & strategy

- Further partner collaborations
- Market access preparation



FluoGuide

Precision surgery improving outcome for cancer patients

