



hemerion

Advancing cancer therapies.
At the speed of light.

Executive summary.

Mission & facts



Hemerion Therapeutics

- develops **#cancer** first in line therapy delivered intraoperatively
- first indication is **#glioblastoma**, the most common and deadliest brain cancer
- has already 2 clinical trials successfully achieved in France
- has shown unprecedented **#positive** outcomes with its **#drug/device** combo technology
- is already **#FDA** (IND) and **#EMA** granted for clinical investigation
- has a **multicentric phase I/II clinical trial in follow-up in the US and EU**
- will ultimately **#challenge radiotherapy** and reshape the cancer treatment paradigm

Inflection points

- 14 M€ raised in funding since inception in sept. 2020
- Orphan Drug Designation at both EMA / FDA
- Pivotal clinical trial for our first indication will be launched in Q4 2026
- Market access in EU and in the USA is planned in early 2030
- Clearing the CE mark is underway (2027)
- Active R&D program to expand to other oncological indications
- Market access strategy already validated with FDA

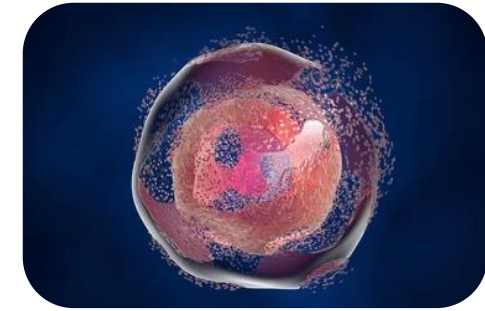


"A new paradigm in oncology care — precision, speed, and impact in one surgical step."

Our breakthrough innovation...

...a **photodynamic therapy** to revolutionize cancer surgery.

Combining a selective photosensitizing drug with a photonic device to specifically kill resistant cancer cells always remaining after surgery



1

A photosensitizing drug, Pentalafen®, is administered prior to surgery

2

During surgery, Heliance®, a dedicated photonic device activates the Pentalafen®

3

Pentalafen® & Heliance® combination destroys remaining cancer cells, preserving healthy ones.

4

Pentalafen® & Heliance® combination achieves efficacy comparable to supramarginal resection without the risks



Pentalafen® bonds only to cancer cells



Independent from genetic typology of tumor cells



Remaining cancer cells are pivotal in the recurrence and exhibit a robust radio-resistance



Infiltrative tumor cells are killed deep within the cavity margins

Our first indication:
**GLIOBLASTOMA (GBM) is the most common and most
devastating brain cancer.**

> 156,000 diagnosed GBM worldwide per year

Current therapies are ineffective!



- Recurrence # 7 months
- Survival rates at 5-year < 6%
- Immunotherapy fails
- GBM stem cells are radioresistant



Standard of Care has a hard impact on **quality of life**



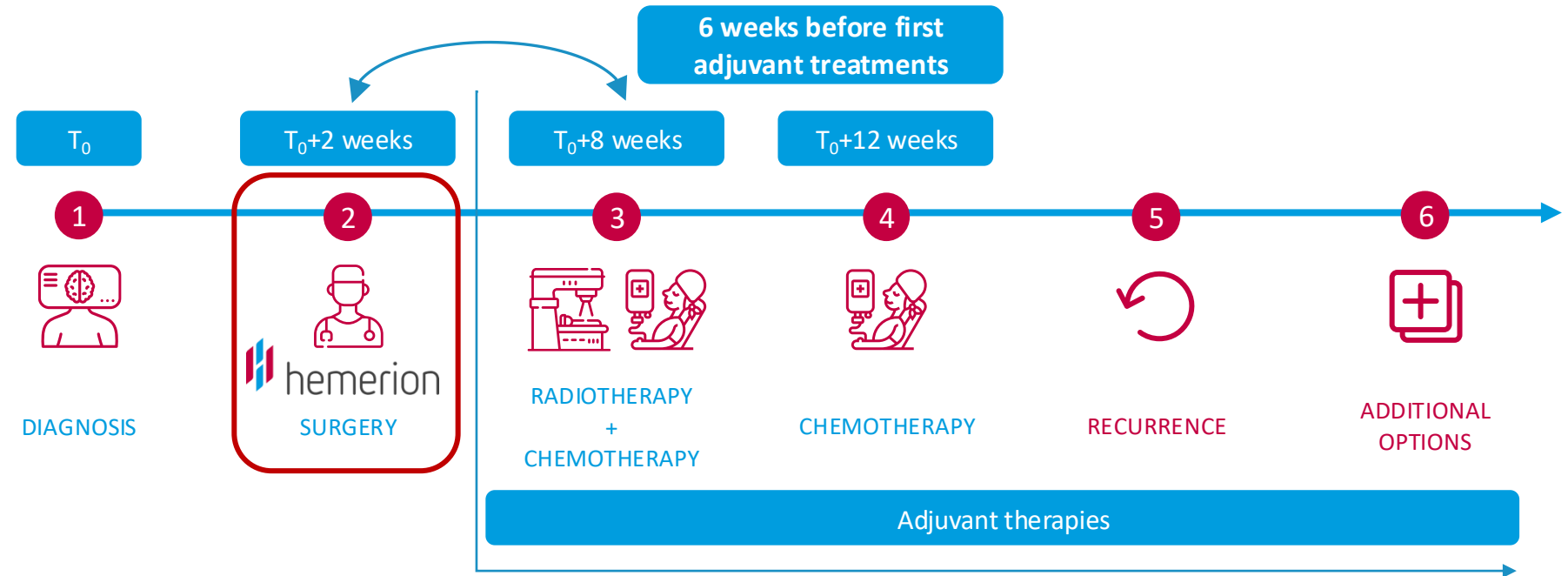
Cost of the standard of care: **€150,000 / patient**



We can and must do better



Hemerion technology is involved very early in the patient's continuum of care
... and will ultimately reshape the Standard of Care.



- + **Patient friendly** (No change to surgical experience)
- + **Seamless integration in the clinical workflow** (one extra step, adding 30 min to surgery)
- + **Preventing tumor recurrence**
- + **Challenge the use of radiotherapy** (improved quality of life, decrease of the economic burden)
- + **Offer new treatment options for managing the recurrence**

An advanced clinical program toward EU/US Market Authorization.

Clinical Evaluation and Regulatory Timeline

- 
- 2017** First-in-Human PoC Phase I Clinical Trial, France
 - 2021** PoC Phase I/II Clinical Trial, France
 - 2022** Orphan Drug Designation granted, FDA & EMA
 - Q2 2023** IND approval from FDA
 - Q1 2024** First-in-Human Phase I/II Clinical Trial, USA
 - Q4 2025** Type C meeting with FDA. Pivotal study design accepted, clinical development strategy greenlighted
 - Q4 2026** Kick-off Pivotal Clinical Trial, USA + EU
 - *Demonstration of clinical superiority on a significant GBM patients cohort before market approval*



HTX-GBM-01 – Pentalafen/Heliance First-in-human study

HTX-GBM-01 Study (NCT05736406)

“A Dose-escalation Clinical Study of Intraoperative Photodynamic Therapy of Glioblastoma”

Phase I/II study: 3 to 12 patients

Sponsor: Hemerion Therapeutics

Site: UPMC, Pittsburgh, PA USA / CHU Lille, France

Investigators:

J. Drappatz, MD, Neuro-oncologist / C. Hadjipanayis MD, PhD, Neurosurgeon

E. Vauleon, MD, Neuro-oncologist / N. Reyns MD, PhD, Neurosurgeon

Objectives:

- Evaluation of Dose Limiting Toxicities (DLT) to define Maximum tolerated dose (MDT) of light
 - 2 light doses : 200 J/cm² and 400 J/cm²
- Progression free survival rate at 6 months
- Overall safety
- Usability of the Heliance®

Update

- 9 GBM patients included
 - 6 in Pittsburgh, USA
 - 3 in Lille, France
- As of last Data Safety Monitoring Board meeting: no toxicity identified at the 200 J/cm² light dose.
- The enrollement is complete
- End of study planned for Q3 2026.

Preliminary results paving the way for a rapid adoption.

- ✓ **Safety**
 - **Heliance® and Pentalafen® combination products have been confirmed to be safe**
- ✓ **Usability**
 - **Full integration into the standard of care**
 - **30 min of additional surgery only, included in the 4-5 hours of standard procedure time**
- ✓ **Feasibility**
 - **No supplemental intervention was needed for the patient**
- ✓ **Acceptance**
 - **Patients discharged normally after the surgery**

Hemerion answers all unmet medical needs in GBM care management.



Hemerion changes the game in oncology

Median Progression Free Survival of
17.1 months vs 7 months

Long term survival*
40% at 5 years vs 6%

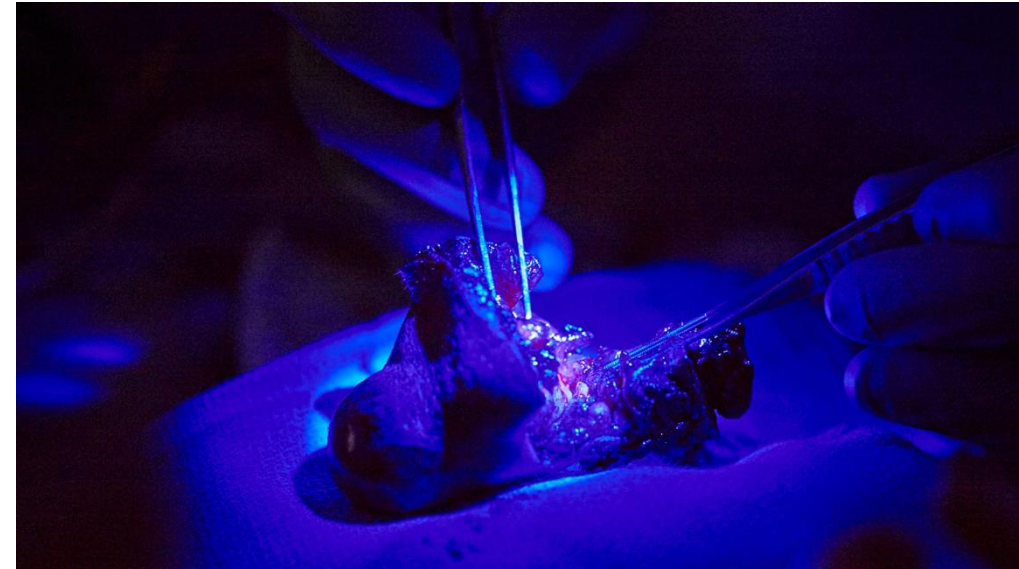
*<https://link.springer.com/article/10.1007/s11060-024-04693-4>

...which can be deployed to other indications in surgical oncology...

Strategic Opportunities

- ✓ For many cancers, **surgical resection will remain the first line treatment**
- ✓ Extent of surgical resection is the most important prognostic factor
- ✓ Pentalafen API fluorescence surgery already evaluated in many indications

- **For most cancers, surgery is the cornerstone of treatment**
 - Primary treatment for 80% of solid cancers
 - Essential for staging and prognosis
- **Surgeons face many challenges in achieving complete tumor removal**
 - Limited visualization
 - Limited access
- **Despite surgery and standard of care, relapse occurs in a significant percentage of patients**
 - Majority of recurrence are local induced by residual cancer cells



And ultimately, **redefining the place of radiation therapy after surgery.**

Strategic Opportunity

- ✓ By fulfilling the same therapeutic role as radiotherapy, Hemerion opens the door to reshaping standard treatment paradigms in oncology.
- ✓ Potential to reduce or adapt radiotherapy in selected cancer indications, improving patient outcomes and quality of life.

- **RT is an adjuvant local treatment:**

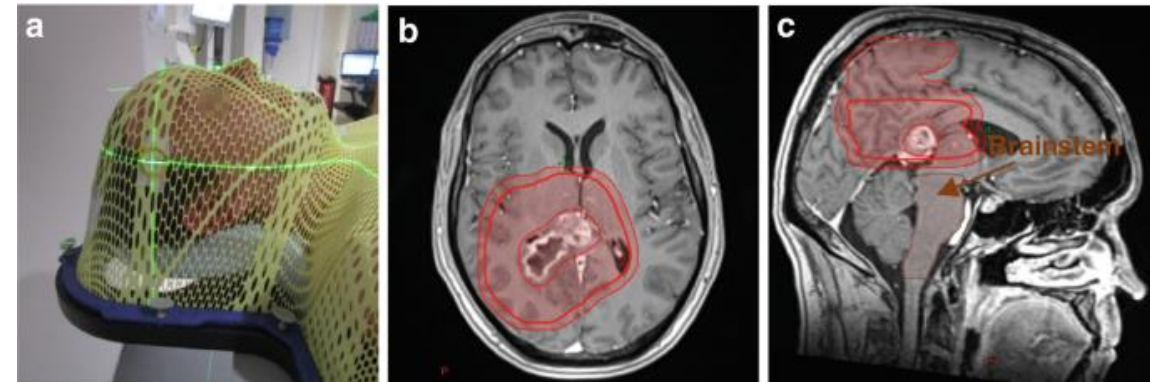
- is used to **reduce the risk of local recurrence by targeting residual cancer cells**
- **is applied during 6-7 weeks** in a Radiation Therapy centers, 5 days a week

- **RT impacts deeply the patient's quality of life**

- Tolerance and adverse events
- Social and Occupational Impact for patients
- Emotional and Psychological Effects

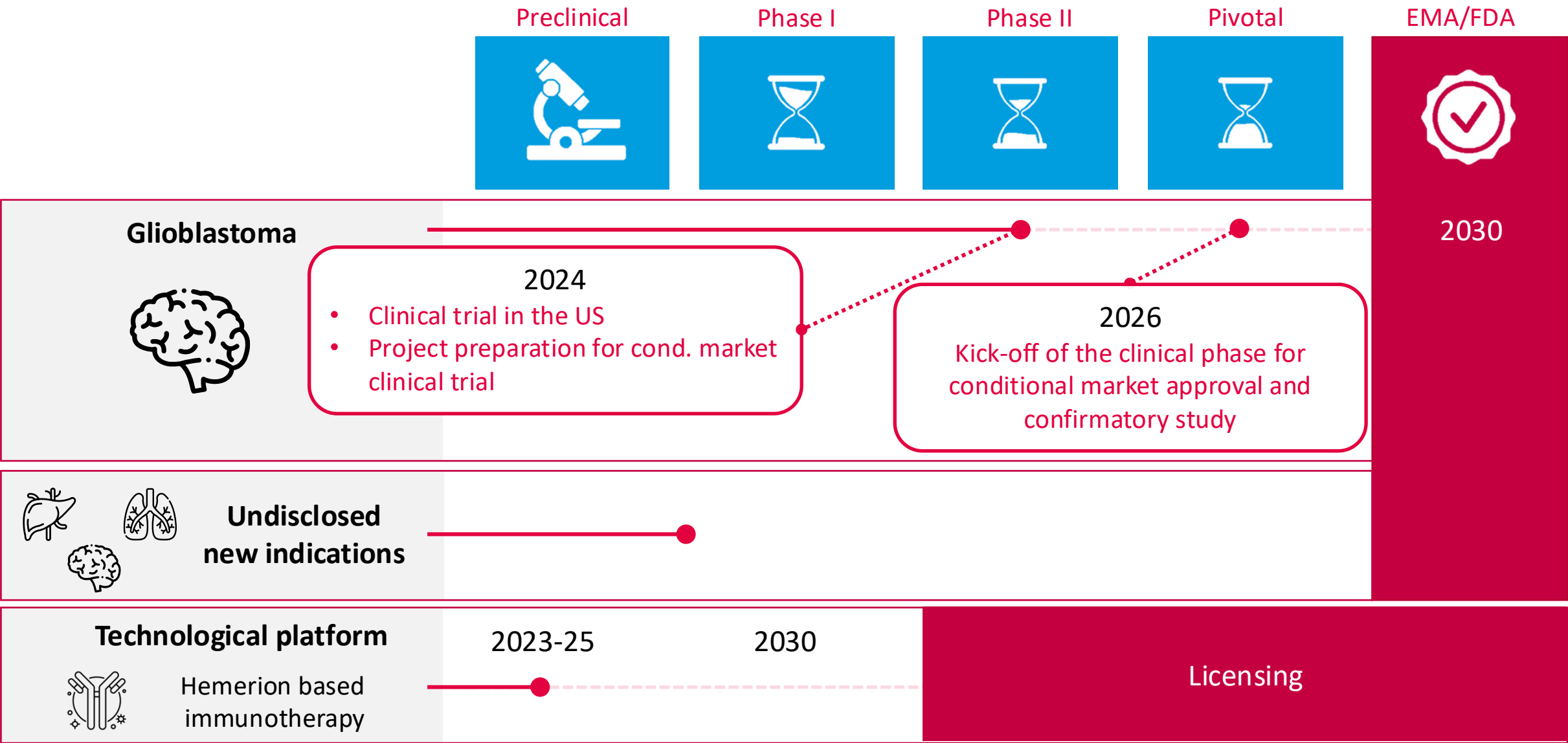
- **RT comes with severe side effects**

- Hair loss, Skin irritation, Nausea and vomiting
- Cognitive and Neurological Effects (Memory Loss, cognitive decline)
- Long term risks such as Radiation Necrosis, vascular changes

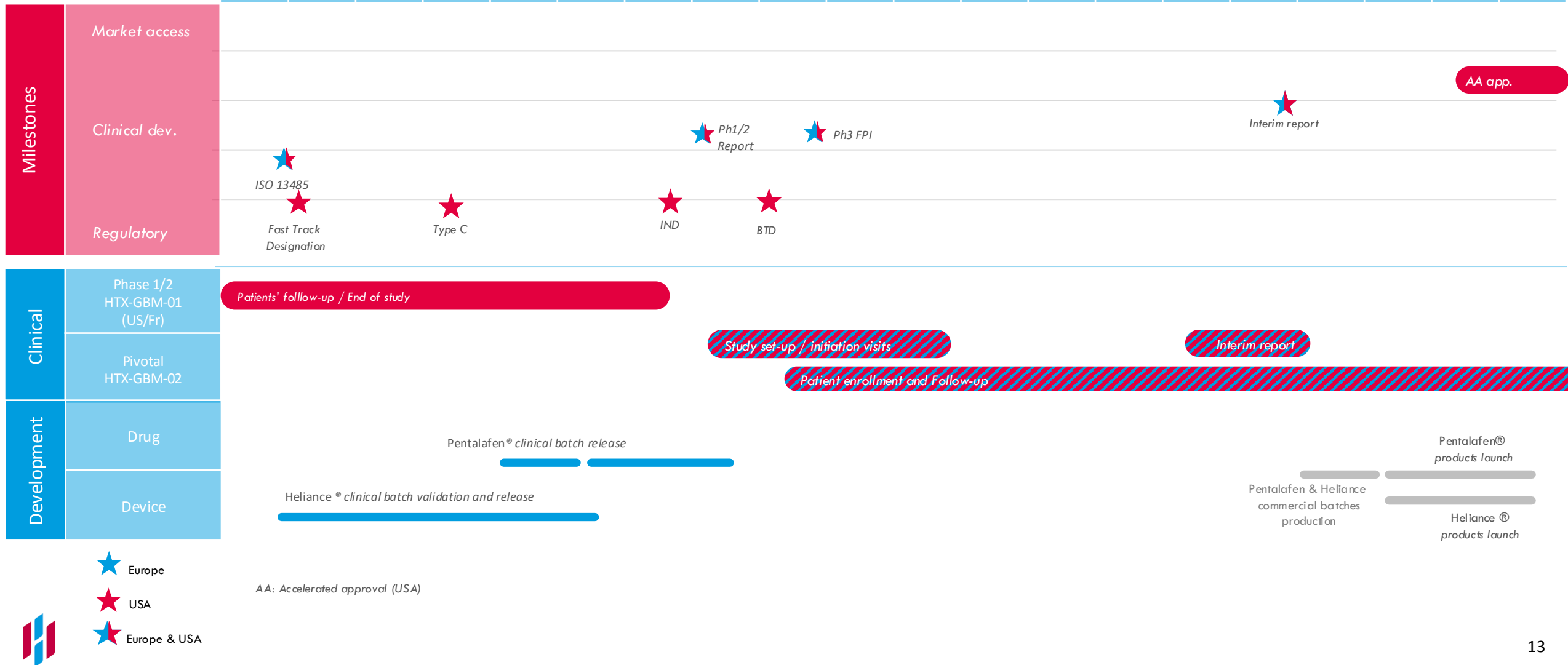


- **RT costs more than \$65,000 (treatment, imaging, follow-up...)**

Pipeline with short and mid-term perspectives.



Roadmap: a clear and comprehensive go-to-market.



A seasoned team with strong track records.



Maximilien Vermandel
CEO - Co-Founder
Over 20 years of research in physics and neurosurgery, Founder of Physics Dept. at Univ. Hosp. of Lille. Associate director of Inserm Lab (U1189)



Clément Dupont
CTO - Co-Founder
Lead investigator in preclinical studies, designer of the medical device used in the clinical trial
Team leader of the European project Synaps project



Michel Andraud
CFO- Co-Founder
30 years as CFO in international industrial and startup companies and in mergers and acquisitions / Cash management oriented



Mélanie Rose
Director of Scientific Innovation & Portfolio Expansion
PhD Immuno-oncology and experienced mass spectrometry researcher (new biomarkers in GBM – Immunology in Brain Cancer)



Antoine Mequignon
Director of Clinical Operations
15 year of long expertise in Phase II/III/IV trial management
With large pharmaceutical groups like Guerbet and Sanofi
Established and managed around 20 large scale clinical trials



Everardo Saad
Medical Director
Medical oncologist by training and a fellow of the MD Anderson Cancer Center. He has over 25 years of experience in oncology and clinical research consulting in world-class CROs.

Team experience & accomplishments

- > **150** scientific articles
- > **30** clinical trials in human health
- > **70 M€** raised with Biotech

Relevant background



Hemerion's team: <https://hemerion.com/expanding-the-limits-of-cancer-therapies/team/>

KOLs – Internationally acknowledged experts in the field.



Pr. Jan Drappatz
PhD, MD, Neurology



Pittsburgh, PA



Pr. Alexandra J. Golby
MD, Neurosurgery



Boston, MA



Ass. Pr. Jennifer Moliterno
MD, Neurosurgery



New Heaven, CT



Pr. Costas Hadjipanayis
PhD, MD, Neurosurgery



Pittsburgh, PA



Pr. Michael Weller
PhD, MD, Neurology



Zurich, Switzerland



Pr. Kambiz Nael
MD, Neuroradiology



Los Angeles, CA



Pr. Jason P Sheehan
PhD, MD, Neurosurgery



Charlottesville, VA

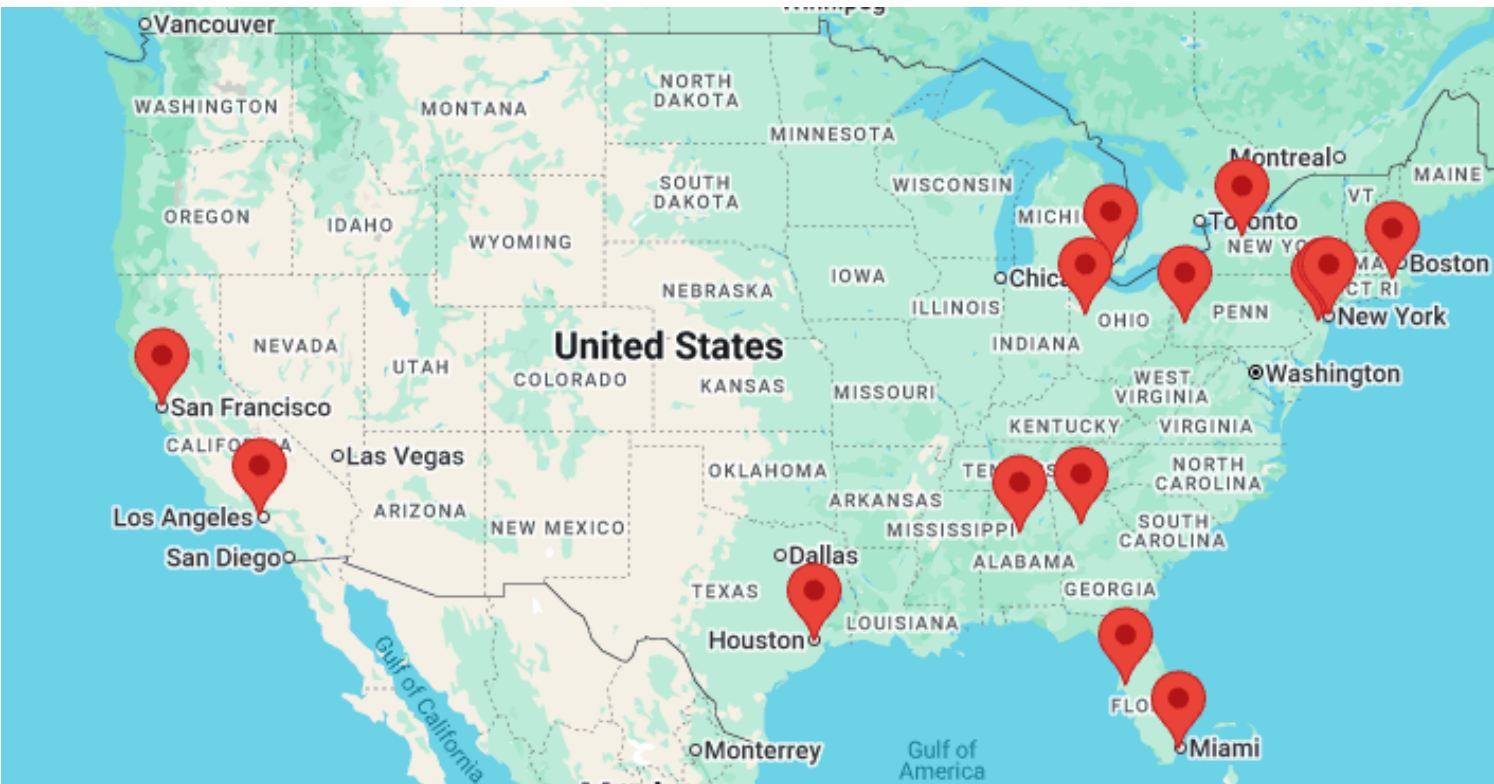


Pr. Nicolas Reyns
PhD, MD, Neurosurgery



Lille, France

Interest from Hospitals – Leading centers ready to integrate our technology



Dr. Ian Y Lee
**HENRY
FORD
HEALTH**

Dr. Daniel Orringer
**NYU Langone
Health**

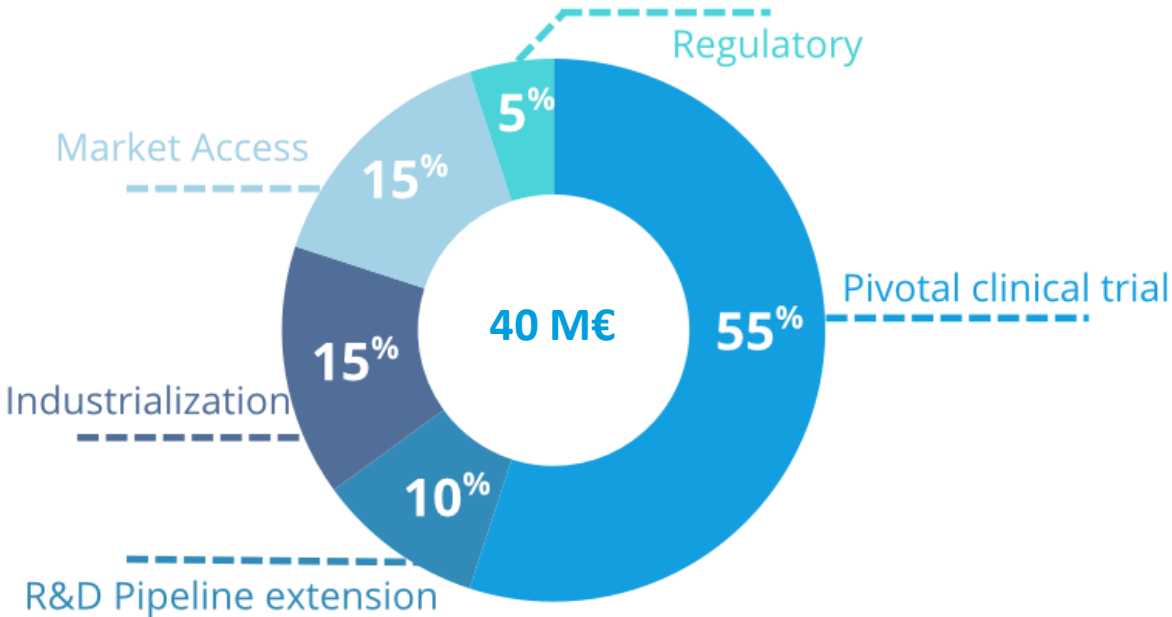
Dr. Mitch Berger
UCSF
University of California
San Francisco

Dr. Kimberly Hoang
EMORY

And others...



40 M€ to launch our first indication and elaborate market access strategy.



Investment Considerations.

A **market-ready** technology ...

... and a **continuous improvement** for shaping the future

Mission & facts

- **Strong preliminary data with PFS > 17 months** and 40% of long-term survival
- **Orphan Drug Designation** at both EMA / FDA
- **Fast Track Designation** granted
- Strong opportunities to expand to other oncological indications
- **Clinical trial in the US/FR** to be achieved in Q3 2026
- **14 M€ raised** since the inception
- **40 M€ needed until market authorization**

Opportunities

- Market Access strategy **validated with the FDA**
- **Full product package** already available for clinical trials and future market launch
- Robust intellectual property portfolio
- **Future indications** in oncology at **minimal R&D costs**
- Synergy of our technology with immunotherapeutic strategies: **a stepstone for strategic exit**
- Leading clinical outcomes will be able to attract **strategic interest** upon market approval in two verticals: pharma & devices





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At the speed of light.

Maximilien VERMANDEL

✉ invest@hemerion.com



Project Summary: <https://youtu.be/nR70M9SJ7fc?si=5H2SSaVGS7lmmTu>