hemerion

PRESS RELEASE

Hemerion Announces Completion of Patient Enrollment in HTX-GBM01 Trial and Accelerates Clinical Development of its Lead Therapy

Contact / Hemerion
Maximilien Vermandel,
Founder - CEO
press@hemerion.com
Mob. +33 (6) 62 78 94 01

Villeneuve d'Ascq, France - May 4, 2026

Villeneuve d'Ascq, France - May 4, 2026

Hemerion Announces Completion of Patient Enrollment in HTX-GBM01 Trial and Accelerates Clinical Development of its Lead Therapy

Following its most recent Independent Data and Safety Monitoring Board (iDSMB) meeting, the French healthtech company announced that it has completed patient enrollment in its HTX-GBM-01 clinical trial of the Pentalafen/Heliance therapy for the treatment of glioblastoma. This major milestone validates Hemerion's clinical roadmap, which aims for a U.S. market launch in 2030.

On April 16, 2026, Hemerion confirmed the enrollment of the last patient in its HTX-GBM-01 clinical trial. This multicenter, Phase 1/2 interventional study aims to investigate and confirm the safety and feasibility of intraoperative Pentalafen® / Heliance® therapy in patients aged 18 to 75 with newly diagnosed glioblastoma.

Led by Jan Drappatz, MD (UMPC in Pittsburgh, USA) and Enora Vauleon, MD (Lille University Hospital, France), the trial included 9 patients and will determine the safety and tolerability of various doses of light added to standard temozolomide-based chemotherapy.
The initial clinical results will be published in the fourth quarter of 2026.

Marketing Authorization Expected in 2030

As a Fast Track designation holder, Hemerion has received the FDA's preliminary endorsement of its clinical development strategy. Specifically, the U.S. regulatory agency has confirmed that its Pentalafen/Heliance therapy is eligible for Accelerated Approval.

This pathway allows therapies targeting serious or life-threatening conditions with unmet medical needs to obtain marketing authorization more rapidly, based on surrogate endpoints. Thanks to this designation, Hemerion now anticipates receiving marketing authorization for the U.S. market in 2030.

Significant Clinical Advance Offers New Hope Against Glioblastoma, One of the Most Aggressive and Treatment-Resistant Brain Cancers

Glioblastoma (GBM) is the most common and most aggressive primary brain tumor in adults, with approximately 160,000 new cases diagnosed worldwide each year, including 33,000 in the European Union and the United States.

The current standard of care — surgery, radiation therapy, and chemotherapy — has remained largely unchanged for nearly 25 years. While surgery aims to remove as much of the tumor as possible without damaging healthy brain tissue, complete resection is rarely achievable due to the highly infiltrative nature of GBM.

Despite this aggressive multimodal approach, patient outcomes remain poor: median survival is only 15 to 17 months, with nearly inevitable recurrence. Only 6% of patients survive five years, largely because residual tumor cells that infiltrate surrounding brain tissue are resistant to current therapies.

The successful completion of Hemerion's HTX-GBM01 clinical trial represents a major step toward transforming this outdated standard of care, which has seen virtually no meaningful progress in over two decades.

Hemerion's Pentalafen/Heliance technology offers a novel approach by selectively destroying residual cancer cells — including those that have infiltrated deep into healthy tissue — without harming surrounding healthy cells. This targeted photodynamic therapy is delivered in a single procedure directly in the operating room immediately following tumor resection, marking a significant advance in the treatment of glioblastoma.

The completion of patient enrollment in the HTX-GBM-01 trial is a decisive milestone for Hemerion. It confirms the strength of our clinical roadmap and brings us closer to our goal: to offer a meaningful new therapeutic solution to patients with glioblastoma — a disease with urgent and unmet medical needs. We are more committed than ever to accelerating the development of the Pentalafen/Heliance therapy and making the prospect of U.S. market approval in 2030 a reality."

Maximilien Vermandel
CEO, Hemerion Therapeutics

Both oncologists and neurosurgeons are very enthusiastic about the potential of Pentalafen®/Heliance® therapy in the treatment of brain cancers. This novel intraoperative approach, administered very early in the standard of care, targets residual glioblastoma cells — precisely where current treatments often fail. It truly changes the game. I am very much looking forward to seeing the safety and efficacy of this treatment confirmed!"

Jan Drappatz, MD
Principal Investigator, UPMC, Pittsburgh, USA

"With this final patient inclusion, Hemerion has demonstrated its ability to successfully conduct the clinical development of its therapy, both in Europe and the United States. Our team has met the combined requirements of the FDA and the EMA. This is clear proof of our maturity and expertise in both operational and regulatory matters."

Antoine Mequignon
Director of Clinical Operations, Hemerion Therapeutics

About Hemerion Therapeutics

www.hemerion.com
Hemerion Therapeutics was founded in 2020 with the mission of developing innovative therapeutic solutions against cancer.
The company's first technology combines a photosensitizing drug (Pentalafen®) with an innovative illumination platform (Heliance®).
This approach is particularly promising for the treatment of glioblastoma, the most common and aggressive primary brain cancer in adults. Hemerion is currently advancing an active clinical program in glioblastoma, with highly encouraging safety and efficacy results to date.

Follow Hemerion on LinkedIn

About the Pentalafen® / Heliance® Combination Therapy

This therapy combines a photosensitizing drug (Pentalafen®) with an innovative illumination platform (Heliance®). It is designed to selectively eliminate residual tumor cells following surgical resection, thereby reducing the risk of recurrence.

Prior to surgery, Pentalafen® is administered to the patient as an oral solution. Within a few hours, its components selectively accumulate in cancer cells but not in healthy cells.
Immediately after tumor removal in the operating room, the surgeon uses the Heliance® platform to deliver a specific wavelength of light that activates the accumulated drug in the cancer cells, triggering their destruction.
The light penetrates deep into the surrounding tissue, destroying residual cancer cells wherever it reaches.

Used intraoperatively right after tumor resection, this therapy has the potential to redefine the standard of care for several types of cancer and to reduce the need for radiotherapy. The first clinical development program focuses on improving the treatment of glioblastoma, the most common and aggressive brain cancer.