



PRESS RELEASE

Positive FDA feedback on Hemerion's clinical strategy for glioblastoma brain cancer therapy

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Hemerion Therapeutics announces the positive outcome of its Type C Meeting with the U.S. Food and Drug Administration (FDA), held in November 2025.

The U.S. health authority confirmed the relevance of Hemerion's proposed clinical and regulatory strategy for the Pentalafen® / Heliance® technology in the treatment of newly diagnosed glioblastoma patients in the United States, and acknowledged the potential eligibility of the therapy for an accelerated regulatory pathway.

As the Phase 1/2 clinical studies for the Pentalafen® / Heliance® therapy near completion, Hemerion received highly positive written feedback from the FDA in December 2025 on its clinical strategy, following a Type C Meeting initiated in November 2025.

These formal meetings allow companies to discuss critical strategic aspects of their clinical and regulatory development programs and to obtain structured feedback from the Agency ahead of subsequent development milestones: an essential step that de-risks the strategy implemented by Hemerion.

FDA Confirms Alignment on a Potential Accelerated Approval Pathway: A major catalyst for Hemerion

Following this exchange, the FDA confirmed the eligibility of the Pentalafen® / Heliance® therapy for the Accelerated Approval pathway. This regulatory mechanism enables earlier market authorization for therapies addressing serious conditions with unmet medical needs, based on a clinically meaningful surrogate endpoint, while confirmatory trials are conducted to support full approval.

This feedback represents a strong positive signal and a significant acceleration opportunity for the development of the Pentalafen® / Heliance® therapy in the U.S. market, potentially enabling market access as early as 2030.

An approved overall clinical strategy

In addition, the FDA confirmed the appropriateness of the overall clinical and statistical approach proposed for the pivotal trial intended to support full regulatory approval at a later stage.

The highly productive exchanges with the FDA also allowed Hemerion's teams to refine and enrich the trial design, enhancing its scientific robustness, statistical power, and clinical relevance.

Pentalafen®: Dual indication validated for Hemerion's lead molecule

The FDA also confirmed the potential for Pentalafen® to cover two complementary indications: fluorescence-guided visualization of tumor cells to optimize surgery, and photodynamic therapy (PDT) to treat residual tumor cells.

This dual indication positions Pentalafen® as a highly differentiated and promising solution within the U.S. neurosurgical oncology landscape.

"This positive feedback from the FDA is both a major milestone and a great success for Hemerion. The potential to pursue Accelerated Approval provides us with a clear roadmap, aligned with the urgent need to deliver new solutions for an extremely aggressive cancer that currently offers little hope to patients.

It also brings important clarity for our financial partners, who can now anchor their investments within an even more precise, structured, and visible development trajectory."



Maximilien Vermandel
CEO, Hemerion

About Hemerion Therapeutics

www.hemerion.com

Founded in 2020, Hemerion aims to develop innovative therapeutic solutions against cancer. Hemerion's flagship technology combines a drug (Pentalafen®) and an innovative illumination platform (Heliance®).

It is particularly promising for treating glioblastoma, the most common and aggressive form of brain cancer, for which Hemerion has an active clinical program showing very promising results in terms of safety and efficacy.

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About the Pentalafen®/Heliance® combined therapy

This therapy combines a photosensitizing drug (Pentalafen®) and an illumination platform (Heliance®). It aims to eliminate residual tumor cells after surgical resection to minimize the risk of recurrence.

Before surgery, Pentalafen® is administered to the patient as an oral solution. Within a few hours, the components of Pentalafen® accumulate in cancer cells but not in healthy cells. Immediately after tumor resection in the operating room, the surgeon uses Heliance® to diffuse a specific wavelength of light that activates the components stored in the cancer cells, triggering their destruction. Cancer cells are destroyed wherever the light penetrates, deep within the tissue.

Used in the OR immediately following resection, this therapy could redefine the Standard of Care for several types of cancer and minimize the need for radiotherapy. The initial clinical development focuses on improving the treatment of glioblastoma.