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PRESS RELEASE

Hemerion announces FDA clearance of IND application for its treatment of glioblastoma, the most aggressive primary brain tumor

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Hemerion announces FDA clearance of IND application for its Pentalafen® / Heliance® combination product in the treatment of glioblastoma, the most aggressive primary brain tumor

Hemerion is a clinical-stage company developing innovative therapeutic solutions for cancer, at the crossroads of medtech and biotech.

The company has received clearance from the U.S. Food & Drug Administration (FDA) for the investigational new drug application (IND) for its Pentalafen® / Heliance® drug-device combination product for the treatment of glioblastoma (GBM). The decision enables Hemerion to proceed with a Phase 1/2 clinical study at University of Pittsburgh Medical Center (UPMC) by Q4 2023.

Glioblastoma is the most common and most aggressive primary brain tumor, with a median ove- rall survival (OS) of 15 months and a progression free survival (PFS) of 7 months only.

Current treatment options (surgery, followed by radiotherapy and chemotherapy) aim at removing or destroying tumor cells inside the brain. They slow the progression of the disease and reduce the symptoms but fail to offer genuine therapeutic solutions. As glioblastoma invades the brain deeply, the current standard of care fails to eradicate all tumor cells. Remaining tumor cells stay active and inevitably recur.

A technology designed to outperform the standard treatments

Hemerion's technology brings a new option to kill these isolated tumor cells, without harming healthy tissue, within the frame of the current standard of care.
Hemerion's drug-device technology combines a photosensitive drug (Pentalafen®) and an innovative laser based illumination platform (Heliance®). This combination product selectively destroys cancer cells without damaging healthy tissue. The Pentalafen® selectively accumulates in cancer cells before surgery. When photoactivated by the illumination platform Heliance®, the drug causes tumor cells death without harming healthy cells.

Tumor cells are eliminated wherever the light penetrates.

A technology that fits seamlessly into the current standard of care

The use of the technology is fast, straightforward, and fits perfectly into the current standard of care :

- The patient is administered a dose of Pentalafen® a few hours before the surgery
- During surgery, after the tumor removal, the surgeon illuminates the cavity with the Heliance® Diffuser for a maximum of 30 minutes to activate the Pentalafen®

The best ever results achieved in a Phase 1 glioblastoma trial

The Pentalafen® / Heliance® combination has already passed several major clinical development milestones, including a Phase 1 trial concluded in 2021, the results of which have been published in the Journal of NeuroOncology. These results validate the feasibility and safety of the treatment and show spectacular preliminary efficacy results, with a more than doubled disease-free life expectancy compared to the current standard of care (17,1 vs.7 months).

Next clinical milestone: a phase 1/2 study in Pittsburgh

The FDA authorization enables Hemerion to commence a Phase 1/2 clinical study at University of Pittsburgh Medical Center by Q4 2023 to evaluate the upgraded Pentalafen® / Heliance® platform. The trial will be conducted under the clinical leadership of Dr Jan Drappatz, MD, neuro-oncologist (Principal Investigator) and Pr. Costas G. Hadjipanayis, MD, neurosurgeon (Co-Investigator).

Ideally positioned for the upcoming Series A financing round

Launched in 2020, Hemerion has successfully raised over €7 million in less than 3 years, enabling our team to implement the next Phase 1/2 study planned in Pittsburgh.

Hemerion actively prepares the next rounds of financing to fund the clinical phases required to obtain Marketing Authorization for its Pentalafen® / Heliance® combination product.

"*We are both delighted and honored to obtain clearance of the IND for our Pentalafen® / Heliance® solution. We are now fully focused on enrolling our first patient to launch the trial as soon as possible*." said Luciola Jauregui Teniente, Head of Regulatory Affairs at Hemerion.

"*The FDA's acceptance of our IND application brings us one step closer to introducing a potentially game-changing treatment for a devastating disease that claims the lives of almost 150,000 patients every year worldwide.*" commented Maximilien Vermandel, CEO of Hemerion.

Pr. Costas G. Hadjipanayis, neurosurgeon and member of Hemerion's Scientific Board, underlines : "*The Hemerion technology is both very advanced and very straightforward to use in the operating room. The concept is very easy to understand and very appealing to neurosurgeons that are mainly frustrated with the current standard of care.*"

Dr. Jan Drappatz, neuro-oncologist and principal investigator, adds: "*GBM is a highly aggressive and difficult-to-treat brain tumor, where treatment options and prognosis have remained largely unchanged for almost two decades. We believe that Hemerion's unique approach may target residual tumor cells in the perioperative field and potentially prolong the time to relapse or death*."

About Hemerion Therapeutics

www.hemerion.com

Founded in 2020, Hemerion is a clinical-stage healthtech company that develops innovative therapeutic solutions for cancer, at the crossroads of biology, physics and surgery.
The first technology developed by Hemerion is a drug-device product combination that com- bines a drug (Pentalafen®) and a laser-based illumination platform. It seamlessly complements neurosurgery, radiotherapy and chemotherapy treatments.
This technology is particularly promising in the treatment of the most common and aggressive brain cancer: glioblastoma, for which Hemerion Therapeutics already has an active Phase 1/2 clinical program that shows very promising safety and efficacy results.
Hemerion believes its proprietary technologies have the potential to become the next standard of care for several cancer types.
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