First U.S. Patients Receive Investigational Bioelectric Therapy for Brain Tumors Under FDA Compassionate Use Request

FDA authorizes single-patient compassionate use of Autem Therapeutics' AutEMsys™ for three patients at Asthra Health



Santa Monica, California Nov 19, 2026 (Issuewire.com) - Patients with brain tumors have begun

receiving AutEMsys, an investigational, non-invasive bioelectric therapy developed by Autem Therapeutics, through the U.S. Food and Drug Administration's (FDA) compassionate use pathway. The FDA has approved single-patient compassionate use requests for three patients under the care of Dr. Santosh Kesari at Asthra Health, a precision medicine practice in Santa Monica, CA. Two have received their first EMF exposure with AutEMsys. They are the first patients in the United States to receive AutEMsys.

Compassionate use allows a patient with a serious or life-threatening condition to receive an investigational medical device outside a clinical trial when no comparable or satisfactory alternative is available. The FDA reviews each request. An institutional review board (IRB) approval (or, for individual patients, IRB chair concurrence), the patient's informed consent, and FDA's determination that the probable risk from the device is not greater than the probable risk from the disease or condition are required.

AutEMsys delivers personalized, low-level, amplitude-modulated electromagnetic frequencies in sessions of about 90 minutes, given two to four weeks apart. Its proposed mechanism of action is that these frequencies may interact with the electrical and metabolic activity of cancer cells, which are different from that of surrounding healthy tissue. The safety and effectiveness of AutEMsys have not been established.

AutEMsys has received FDA Breakthrough Device designation for the treatment of advanced hepatocellular carcinoma (HCC), the most common form of liver cancer. In a feasibility study at Hospital Sírio-Libanês in São Paulo, Brazil, 66 patients with advanced HCC received 539 treatment sessions. From April 2019 to July 2025, more than 250 patients with cancer were enrolled in the hospital's compassionate access program, including 93 patients with high-grade gliomas. Use of AutEMsys for brain tumors is investigational and is not covered by the Breakthrough Device designation.

"Our core mission at Asthra Health is to give patients access to innovative options, with appropriate regulatory and ethical oversight, while the science continues to develop," said Dr. Santosh Kesari, Founder of Asthra Health.

NOTICE: AutEMsys™ is an investigational device. It is not FDA-approved and is not available for commercial distribution. The safety and effectiveness of AutEMsys have not been established. Investigational Device Compassionate Use Requests are authorized by the FDA on a case-by-case basis. FDA authorization is not an FDA approval or a finding of safety or effectiveness. Eligibility is determined individually; this announcement is for informational purposes only and is not an offer of treatment.

ABOUT ASTHRA HEALTH

Asthra Health is a precision medicine practice in Santa Monica, California, specializing in cancer, neurology, and autoimmunity. Founded by Dr. Santosh Kesari, a neuro-oncologist who has treated and researched brain tumors for **27 years and** has authored more than 500 publications, Asthra Health combines advanced diagnostics, personalized treatment planning, and access to clinical research. Dr. Kesari also serves as Chair of the Scientific Advisory Board of CureScience Institute, a nonprofit research organization that partners with Asthra Health to advance translational research, precision medicine, and innovative approaches for cancer treatment. Learn more at asthrahealth.com and curescience.org.

ABOUT AUTEM THERAPEUTICS

Autem Therapeutics is a privately held oncology therapeutic and bioelectric technology company headquartered in Hanover, New Hampshire. The company is developing AutEMsys™, a non-invasive treatment platform that delivers personalized, amplitude-modulated electromagnetic frequencies to patients with hepatocellular carcinoma and other solid tumors. AutEMsys has received FDA Breakthrough Device designation for the treatment of advanced HCC. Learn more at autemtherapeutics.com.



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