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Siren Biotechnology Announces FDA Clearance of Investigator-Initiated IND to Advance Phase 1 Study in Recurrent High-Grade Glioma

SAN FRANCISCO, CA [Mar. 23, 2026] – Siren Biotechnology today announced that the U.S. Food and Drug Administration (FDA) has cleared an Investigational New Drug (IND) application submitted by the University of California, San Francisco to initiate a Phase 1 clinical study evaluating the safety and biologic activity of SRN-101 in adult patients with recurrent high-grade glioma. The IND clearance enables the launch of a single-center, investigator-initiated Phase 1 study led by Nicholas Butowski, MD, Professor of Neurological Surgery and Neuro-Oncology at UCSF.

“This IND clearance allows us to begin evaluating this novel investigational approach in patients with recurrent high-grade glioma,” said Dr. Butowski. “This early-phase study will provide important safety and translational data to help inform future clinical development.”

SRN-101 is an investigational gene therapy developed by Siren Biotechnology. Siren is providing study drug and collaborating with UCSF in support of the trial.

“We are honored to support Dr. Butowski and the UCSF team in advancing this investigator-initiated study,” said Nicole K. Paulk, PhD, Founder, CEO, and President of Siren Biotechnology. “UCSF has long been a leader in neuro-oncology research, and we are excited to contribute to this important effort on behalf of patients with recurrent high-grade glioma.”

This research was additionally made possible by funding from the California Institute for Regenerative Medicine (CIRM), a state of California Agency that funds regenerative medicine, stem cell, gene therapy research and clinical trials (Grant number: TRAN1-15325).

“People with recurrent high-grade glioma urgently need more effective treatment options,” said Ross Okamura, PhD, Research Fellow in Preclinical Development at CIRM. “The launch of this trial at UCSF is a major step toward identifying new options and providing hope for people with this deadly condition.”

About Recurrent High-Grade Gliomas

Recurrent high-grade gliomas are among the most aggressive and lethal brain tumors. Current treatments can include surgery, radiation, and chemotherapy, all of which offer limited benefit. Novel therapeutic approaches are urgently needed.

About the University of California, San Francisco (UCSF)

The University of California, San Francisco (UCSF) is exclusively focused on the health sciences and is dedicated to promoting health worldwide through advanced biomedical research, graduate-level education in the life sciences and health professions, and excellence in patient care. UCSF Health, which serves as UCSF's primary academic medical center, includes among the nation's top specialty hospitals and other clinical programs, and has affiliations throughout the Bay Area. UCSF School of Medicine also has a regional campus in Fresno. Learn more at <https://ucsf.edu> or see our Fact Sheet.

About the California Institute for Regenerative Medicine (CIRM)

The California Institute for Regenerative Medicine (CIRM) is a state Agency created by California voters to accelerate stem cell and gene therapies for people with unmet medical needs. Since 2004, Californians have entrusted CIRM with \$8.5 billion to accelerate promising discoveries through clinical trials, train a regenerative medicine workforce, strengthen the state's biotechnology economy, and expand access to transformative treatments. Today, CIRM is pioneering new models of therapy development and accelerating medical breakthroughs that change lives — in California and around the world. For more information, visit www.cirm.ca.gov.

About Siren Biotechnology

Headquartered in San Francisco, California, Siren Biotechnology is sounding the alarm against cancer. The company is pioneering Universal AAV Immuno-Gene Therapy, a novel therapeutic modality that combines the precision and durability of AAV gene therapy with the immune-modulating potential of cytokine-based approaches. Siren's platform is designed to support localized, sustained immune activation across solid tumors. To learn more, visit sirenbiotechnology.com, and follow us on [LinkedIn](#), [Facebook](#), and [X](#).

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Forward-Looking Statements

This press release contains forward-looking statements related to the initiation, timing, and conduct of clinical trials and the development of investigational therapies. These statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied. SRN-101 is an investigational product and has not been approved by the FDA for any indication. Neither UCSF nor Siren Biotechnology undertakes any obligation to update these statements except as required by law.