Adze Biotechnology Announces Orphan Drug Designation Granted to Adze-1.17-CD40L for the treatment of Malignant Glioma

Adze-1.17-CD40L is a systemically deliverable, conditionally replicative oncolytic virus that delivers recombinent human CD40 ligand locally into solid tumors.

CORAL GABLES, FLORIDA, UNITED STATES, February 7, 2023 /EINPresswire.com/ -- Adze Biotechnology, Inc., a preclinical-stage biopharmaceutical company committed to the development of therapeutics for oncology, announced today that the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for Adze-1.17-CD40L, for treatment of Malignant Glioma. Adze-1.17-CD40L is a systemically deliverable, conditionally replicative oncolytic virus that delivers a recombinent human CD40 ligand locally into solid tumors.

> The novel Adze-1.17 oncolytic immunotherapy platform is designed for both systemic and intra-tumoral delivery of immunotherapy payload combinations to various types of solid tumors."
>
> *Sidney Hopps, CEO*

"This important designation is a milestone in the development of our Adze-1.17 oncolytic immunotherapy platform and highlights the need for potential new treatment options for patients with Malignant Gliomas and other difficult to treat cancers," said Sidney Hopps, Chief Executive Officer of Adze Biotechnology. "The novel Adze-1.17 oncolytic immunotherapy platform is designed for both systemic and intra-tumoral delivery of immunotherapy payload combinations to various types of solid tumors. We look forward to advancing this therapy into the clinic."

FDA Orphan Drug Designation is granted to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the United States.
Orphan drug status provides benefits to drug developers, including:

- assistance in the drug development process
- tax credits for clinical costs
- exemptions from certain FDA fees
- seven years of post-approval marketing exclusivity.

Adze plans to begin clinical trials in 2024 in melanoma in using Adze systemically deliverable oncolytic immunotherapies. Additionally, clinical trials in prostate cancer are being planned for 2025.

About the Adze Oncolytic Immunotherapy Platform

Adze-1.17 is an oncolytic immunotherapy platform designed for systemic delivery of immune-stimulatory transgenes and checkpoint inhibitors to distant and local tumors. The Adze oncolytic platform has been engineered to evade the liver for systemic delivery, and features several retargeted sub-platforms tuned for specific cancer tissue targeting. Adze immunotherapies are designed to deliver clinically validated immunotherapy payloads at high concentrations into tumors while restricting replication to cancer cells.

About Adze

Adze Biotechnology, Inc., headquartered in Coral Gables, FL, was established in 2020 to develop a platform of novel systemically deliverable oncolytic immunotherapies. Adze's proprietary oncolytic platform is based on a potent chimeric adenoviral backbone with the capacity to provide customized payloads that can be added at will. These payloads can be designed to recruit and enhance patient immune systems, to treat their own cancers, maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The Adze-1.17 platform exhibits a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of tumors, resulting in the release of tumor derived antigens that alter the tumor microenvironment (TME) to promote a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities. The Adze-1.17 platform, with an attractive safety profile, has the versatility to be developed alone or combined with a variety of other treatment options. For more information, please visit Adzebiotech.com

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