

# Marin Biologic Laboratories Co-Authors Breakthrough AAV Gene Therapy Study

*Company's assay development and IND-enabling studies support advancement of innovative AAV-delivered immunotherapy*

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*Tania Weiss, Ph.D.*

Laboratories is excited to announce its pivotal role as co-author and scientific contributor to a groundbreaking study featuring VNX-101, an adeno-associated virus (AAV)-based gene therapy developed to target CD19-positive B cell malignancies. The study, newly published online in *Molecular Therapy: Methods & Clinical Development*, represents a significant leap forward in the creation of durable, off-the-shelf cancer immunotherapies.

The research was led by experts at The Abigail Wexner

Research Institute at Nationwide Children’s Hospital sponsored by Vironexis Biotherapeutics. Notably, results illustrate that a single intravenous dose of VNX-101 achieves prolonged expression of GP101, a bispecific T cell engager engineered to replicate the effectiveness of the FDA-approved blinatumomab, but with innovative safety enhancements designed to minimize immune responses.

Preclinical results showed that VNX-101 delivers sustained antitumor activity in mouse and non-human primate models without inducing significant toxicities, pointing to its potential as a safer, more scalable immunotherapy platform.

Preclinical studies in mice demonstrated anti-tumor efficacy and supported favorable toxicity and biodistribution profiles, while non-human primate studies were conducted specifically to assess safety and pharmacokinetics. Together, the data indicate that VNX-101 provides sustained therapeutic activity without significant toxicity, highlighting its potential as a safe and accessible immunotherapy.

Marin Biologic Laboratories acted as the project’s contract research organization (CRO), bringing essential expertise in assay development, product characterization, and the execution of IND-enabling studies necessary for clinical advancement.

“We are proud to be part of this groundbreaking research,” said Tania Weiss, Ph.D., CEO of Marin

Biologic Laboratories. "Our team is dedicated to accelerating the next generation of cell and gene therapies by providing rigorous, science-based CRO support from discovery through regulatory approval."

A Phase I/II clinical trial evaluating VNX-101 in patients with relapsed or refractory CD19+ malignancies is currently underway (ClinicalTrials.gov Identifier: NCT06533579).

Reference: Development of VNX-101, an Adeno-Associated Virus with Less Immunogenicity and Efficient Long-Term Expression of a CD19 T-Cell Engager. Molecular Therapy Methods & Clinical Development, published online July 24, 2025; DOI: 10.1016/j.omtm.2025.101541

About Marin Biologic Laboratories Inc.

Marin Biologic Laboratories (MarinBio) is a woman-owned contract research organization (CRO) with over 30 years of experience supporting the pharmaceutical and biotech sectors. Specializing in custom cell-based assays, GMP(<https://www.marinbio.com/services/cgmp-services-ind-nda-bla-commercialization/>) /GLP (<https://www.marinbio.com/services/cgmp-services-ind-nda-bla-commercialization/>) compliance, and regulatory strategy, MarinBio partners with clients to advance therapeutics from discovery to commercialization. With a team of senior PhD scientists and a flawless regulatory audit history, MarinBio provides the scientific expertise and quality systems necessary to meet global compliance standards.

MarinBio is recognized for its scientific agility, rigorous quality systems, and deep understanding of FDA regulatory expectations. The company is known for working collaboratively with clients, ensuring each assay is customized to meet specific regulatory, technical, and commercial goals. Operating from a GMP-compliant facility in Novato, CA, MarinBio supports US and international clients ranging from venture-backed startups to top-tier global biopharma firms.

About Vironexis Biotherapeutics

Vironexis is focused on transforming the future of cancer treatment by pioneering AAV-delivered T-cell immunotherapy. Our TransJoin™ AAV Gene Therapy Platform enables the creation of off-the-shelf, single-dose gene therapies designed to overcome the key challenges and shortcomings of current immunotherapies, including CAR-T and bispecific antibodies. Our current pipeline includes more than ten product candidates for blood-based cancers, solid tumor metastasis prevention, and a cancer vaccine. Our lead clinical program, VNX-101, is for the treatment of CD19+ leukemias and lymphomas. Visit us at <https://vironexis.com/>.

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