

First Subject Dosed in Phase 1 Clinical Trial for CAY001 for Life-Threatening Hemorrhage

NEW YORK, NY, UNITED STATES, December 15, 2025 /EINPresswire.com/ -- [Cayuga Biotech](#), Inc., a clinical-stage company developing novel therapeutics to address hemorrhage, today announced that the first subject has been dosed in its Phase 1 clinical trial of CAY001, a first-in-class, synthetic polyphosphate-silica nanoparticle (polyP-SNP) complex. CAY001 is being developed as a single-dose treatment to address current gaps in care that result in nearly 2 million hemorrhage deaths annually.

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*Andrea-Ashford Hicks, CEO,
Cayuga Biotech*

Hemorrhage is often the underlying cause of death related to use of blood thinners, surgery, trauma and childbirth. Current treatments do not address non-compressible bleeding -- such as intracranial or from penetrating injury -- quickly enough nor do they address many types of coagulation dysfunction.

“We are excited to be on our way to generate Phase I

safety and efficacy data for CAY001 following the consistently compelling preclinical results we've seen,” said Andrea Ashford-Hicks, Chief Executive Officer, Cayuga Biotech. “There has been a dearth of novel approaches to address one of the most fundamental problems in human health, and it is our hope to fulfill this significant unmet need with CAY001.”

The Phase 1 clinical trial is a randomized, placebo-controlled, single-ascending dose study in 24 healthy volunteers (NCT06845839) to assess the safety, pharmacokinetics and pharmacodynamics of CAY001 over a 28-day period following intravenous administration. The trial is expected to conclude in the first half of 2026.

CAY001 accelerates the clotting response specifically at the site of bleeding by mimicking the activity of endogenous platelet polyP. Its potential as a universal hemostatic drug has been established in preclinical models, demonstrating rapid halt of life-threatening bleeding and the ability to overcome challenging types of coagulation dysfunction.

About Cayuga Biotech, Inc.

Cayuga Biotech is a clinical-stage company developing novel therapeutics to address hemorrhage by harnessing the body's innate ability to stop bleeding. Cayuga's pipeline includes

CAY001 (polyP-SNP complex) in development for life-threatening major hemorrhage; CAY002, a discovery-stage program for inherited bleeding disorders, and; a portfolio of additional early-stage programs across the healing continuum. Treatment of bleeding is the first of many therapeutic applications for Cayuga's proprietary polyP platform. For more information visit www.CayugaBiotech.com.

Disclaimer

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