

Macro Biologics IND Accepted by FDA for Amicidin- α Surgical Gel's Phase 1 Clinical Trial

Amicidin- α Surgical Gel is designed to protect the vulnerable tissues of surgical and traumatic wounds and reduce the risk of infection

CARLSBAD, CA, UNITED STATES, June 18, 2026 /EINPresswire.com/ -- [Macro Biologics](#), Inc., is an advanced biomaterials company developing innovative products for healthcare and beyond. Today, the Company announced that it has received a "Study May Proceed" letter from the U.S. Food and Drug Administration for its Investigational New Drug application for Amicidin- α Surgical Gel. The accepted IND supports initiation of a clinical trial entitled, "A Phase 1 Study to Assess Safety and Tolerability of Intrawound Application of Amicidin- α Surgical Gel in Adult Patients", which will evaluate the safety and tolerability of Amicidin- α Surgical Gel when applied directly into surgical wounds.

Macro

Biologics



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*Dr. Michael P. Bevilacqua, CEO
& CSO of Macro Biologics*

Amicidin- α is a synthetic amino acid polymer engineered to protect the exposed tissues of surgical and traumatic wounds. It has a dual “block and kill” mode of action that combines physical barrier properties with broad microbicidal activity. Amicidin- α Surgical Gel is being developed initially for direct application into surgical wounds to help reduce the risk of serious post-operative infections.

“Receiving FDA clearance to proceed with this Phase 1 study is an important milestone for our Amicidin

technology,” said the CEO and CSO of Macro Biologics, Michael P. Bevilacqua, MD, PhD. “Our top priority is to create a new generation of advanced biomaterials that can protect at-risk patients in hospitals, ORs, ERs, and military from life-threatening infections. We are excited to move Amicidin- α Surgical Gel into clinical development.”

[Curapath](#), a leading contract development and manufacturing organization (CDMO) specialized in polymer-based therapeutics and drug delivery systems, has supported Macro Biologics in the development and manufacturing of both the Amicidin-α drug substance and the Amicidin-α Surgical Gel drug product. The collaboration has supported the program from early process development through GMP manufacturing, enabling the IND submission and the supply of clinical trial material for the upcoming Phase 1 study.

“We are delighted to see Amicidin-α Surgical Gel reach this important clinical milestone. Supporting innovative companies such as Macro Biologics in the transition from development to the clinic is at the core of what we do at Curapath. This achievement reflects the strength of our collaboration and the dedication of both teams, and we look forward to continuing to support the advancement of this promising technology as it progresses through clinical development,” said Philippe Clavel, CEO of Curapath.

Amicidin-α Surgical Gel is investigational and has not been approved by the FDA for commercial use.

About Macro Biologics

Macro Biologics, Inc. designs, patents, and produces advanced biomaterials for safer healthcare, clean water and food, and better packaging. The Company's lead Amicidin programs are designed to protect at-risk patients by guarding vulnerable tissue gateways from infection. The Macro technology platform and product pipeline are supported by a strong intellectual property portfolio.

About Curapath

Curapath is a contract development and manufacturing organization (CDMO) specializing in polymer and lipid-based therapeutics, drug delivery systems and nanoparticle technologies. The company supports pharmaceutical and biotechnology partners through process development, analytical services, GMP manufacturing and fill-finish operations, helping accelerate the path from early development to clinical and commercial supply.

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