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Amicidin-α Prolonged Field Care Powder & Surgical Gel to Protect Wounds from Point-of-Injury through Definitive Care

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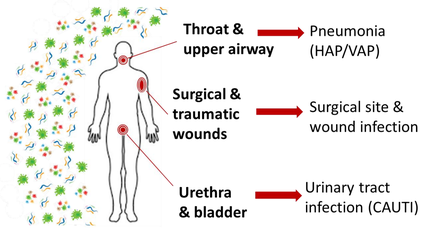
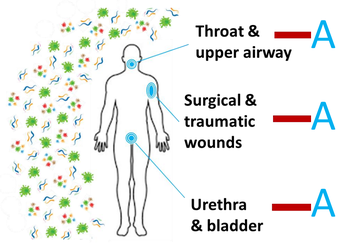
Medical Approach

Life-threatening Infections…



…begin at "gateways"

Guard the "gateways"…



…locally with Amicidins

Technology: Amicidins™

Amino Acid Polymers Engineered for Local Application:

1. **Beneficial physical MOA**
   Barrier to block or surfactant to cleanse
2. **Broad microbicidal MOA**
   Including drug-resistant bacteria & Candida
3. **Safety**
   For people and the environment

Broadly Microbicidal

Amicidins kill (partial list):

Gram-Positive Bacteria
- *S. aureus* (incl. MRSA)
- *S. epidermidis* (incl. methicillin-res.)
- *E. faecalis*
- *E. faecium* (incl. vancomycin-res.)
- *S. pyogenes*

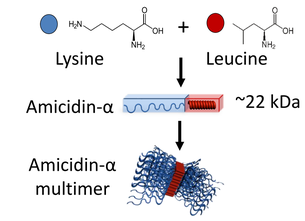
Gram-Negative Bacteria
- *A. baumannii* (incl. pan-res.)
- *P. aeruginosa* (incl. multidrug-res)
- *K. pneumoniae* (incl. KPC, ESBL+, CRE)
- *E. coli* (incl. ESBL+)

Yeast
- *C. albicans* (incl. fluconazole-res.)
- *C. auris*
- *M. pachydermatis*

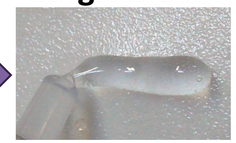
1 Amicidin, 2 Formulations

Amicidin-α

To protect clean/near-clean tissues



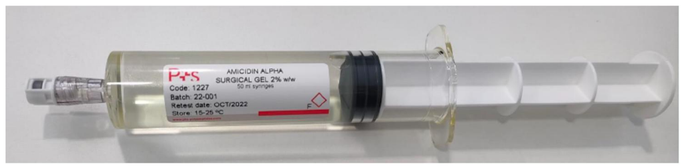
Surgical Gel



Prolonged Field Care

Amicidin-α Surgical Gel

IND# 140908 – "Study May Proceed" Letter Received



Nonclinical Pharmacology Summary

>99.9% kill in 2 *in vitro* and 4 *in vivo* models

	Model	Microbes	Key Results
in vitro	VITRO-SKIN	*S. aureus*	>99.9% reduction
	Porcine skin explant	*P. aeruginosa*	>99.9% reduction
in vivo	Porcine incisions	*S. aureus*	>99.9% reduction
	Porcine excisions	*S. aureus* or mixed inoculum	>99.9% reduction
	Rat wound with mesh	*S. aureus,* MRSA, or *P. aeruginosa*	>99.9% reduction (tissue & mesh)
	Rat orthopedic wound	MRSA or *P. aeruginosa*	>99.9% reduction; blocked invasion

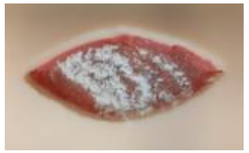
Nonclinical Safety Summary

NOAELs at highest doses tested

GLP Safety Studies	Species	Key Observations
Dermal Irritation	Rabbit	All zero scores – a "non-irritant"
Dermal Sensitization	Guinea Pig	All zero scores – a "non-sensitizer"
Cardiopulmonary Safety Pharmacology	Minipig	No adverse cardiopulmonary effects
CNS/FOB Safety Pharmacology	Rat	No adverse CNS/FOB effects
Intraoperative Dose Escalation in Wounds	Rat	NOAEL highest tested – 172 mg/kg No target organ of toxicity identified
Intraoperative Dose Escalation in Wounds	Minipig	NOAEL highest tested – 174 mg/kg No target organ of toxicity identified No antigen in plasma by Simoa

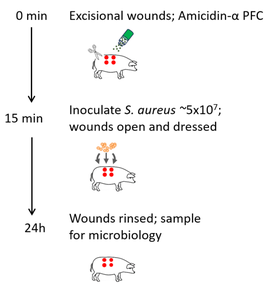
Amicidin-α PFC

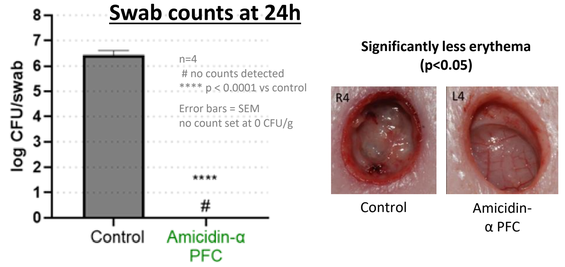
(Prolonged Field Care)



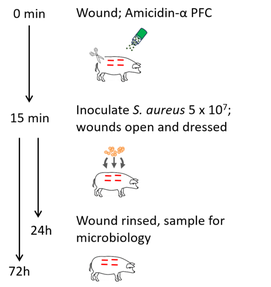
Dry powder formulation of Amicidin-α
Hydrates immediately upon exposure to moisture to form an antimicrobial barrier hydrogel

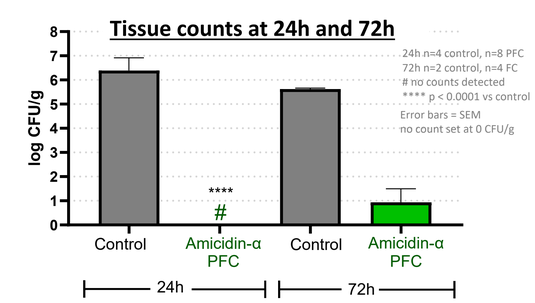
Blocks Wound Contamination





Protects Wounds for 72h





Clinical Development

Phase 1 Clinical Trial Outline

"A Phase 1 Study to Assess Safety and Tolerability of Intrawound Application of Amicidin-α in Adult Patients"

Trial objectives: 1. Assess the overall safety and tolerability of intrawound Amicidin-α
2. Assess potential systemic absorption of Amicidin-α in plasma; and
3. Investigator feedback on product ease of use and volume adequacy.

Amicidin-α Surgical Gel Only Component

Population: ~40 adult patients undergoing an interventional procedure on trunk, arms, or leg exposing subcutaneous tissue, muscle, and/or intact bone with wound ≥5 cm (e.g., skin lesion removal, mastectomy)

3 Cohorts: (1) 2 SOC only & 6 SOC + Surgical Gel (up to 25mL, rinsed out);
(2) 3 SOC only & 9 SOC + Surgical Gel (up to 50 mL, rinsed out);
(3) 5 SOC only & 15 SOC + Surgical Gel (Up to 50mL; 2mm coating left in)

Assessments: Screening, pre-op, post-op 1h, 4h, 48-72h, Day 7, Day 14, Day 30

Trial Expansion to Include Amicidin-α PFC

Population: ~20 adult patients with wounds ≥5 cm, requiring delayed primary closure, healing by secondary intention, or follow-on surgery

3 more cohorts: (1) 6 Amicidin-α PFC (up to 2g, rinsed out at 48-72hr);
(2) 14 Amicidin-α PFC (up to g; rinsed out at 48-72hr)

Assessments: Screening and post-treatment 1h, 4h, 48-72h, Day 7, Day 14, Day 30

Note: Study may proceed letter was received for performance of the Amicidin-α Surgical Gel only component of the above development plan. Feasibility of performing the Amicidin-α PFC expansion awaits confirmation from the FDA.

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