CLARAMETYX biosciences

Pioneering therapeutic solutions for bacterial biofilm-related chronic respiratory disease

GET TO KNOW CLARAMETYX

- Location: Columbus, Ohio
- Year Founded: 2020
- Clarametyx Biosciences is combating the formidable challenge of persistent and recalcitrant infections through an innovative technology platform targeting the biofilm—a protective layer around bacteria—to enable a more effective immune response and antibiotic intervention. The Columbus, Ohio-based company is building a pipeline of therapeutic antibodies and vaccines for chronic respiratory infections associated with biofilms.

MANAGEMENT TEAM

David V. Richards, CEO
Charles McOsker, PhD, CSO*
Veronica Hall, PhD, COO
Steve St. Onge, PharmD, SVP - Corp Dev.

COLLABORATIONS/PARTNERS

Licensed from Nationwide Children's Hospital, Columbus Cystic Fibrosis Foundation, Phase 2 Trial Partner
CARB-X, Funding Support

OPEN TO STRATEGIC PARTNERSHIPS

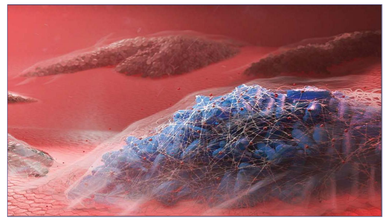
Seeking strategic partnerships to further advance the development of CMTX-101 therapeutic and CMTX-301 vaccine platforms

CONTACT

Charles McOsker PhD
cmcosker@clarametyx.com
www.Clarametyx.com

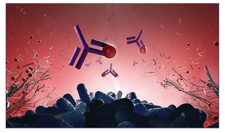
Significant Burden of Biofilms

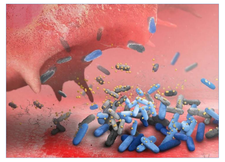
- Well-established that biofilms are associated with acute and chronic pulmonary disease, including CF, non-CF bronchiectasis, and NTM lung disease[1,2]
- Biofilms protect bacteria against antibiotic and immune attack, drive inflammatory responses and worsening lung function, and contribute to antibiotic resistance development



Anti-Biofilm Platform

- CMTX-101 is a novel anti-biofilm antibody that captures and removes these DNABII proteins[4]
- Enables antibiotic intervention and prevents biofilm formation, *yet does not disrupt the gut microbiome*

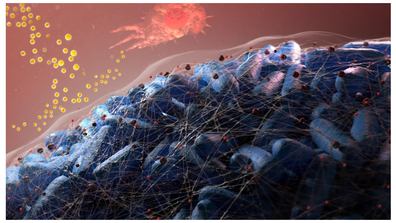




1. **Immune Effectors Can Efficiently Clear Bacteria**
2. **Improves Antibiotic Effectiveness**
3. **Reduces Inflammation to Improve Recovery**

Discovery: Linchpin Proteins

- Bacterial biofilms contain linchpin DNABII proteins that stabilize an extracellular DNA (eDNA) structure[3]
- DNABII proteins are ubiquitous across bacterial pathogens and are not found in mammalian cells
- Universal target for disruption of biofilm matrix



Broadly Applicable Pipeline

- Common respiratory inflammatory diseases are broadly addressable through biofilm-targeting strategy
- Multi-modal platform pursuing both therapeutic and prevention approaches
- **Anticipating interim read-out of CMTX-101 in people with CF and *Pseudomonas aeruginosa* mid-2025**

PLATFORM PROGRAM	DRUG MECHANISM	TARGET INDICATION(S)	DEVELOPMENT STAGE
			LEAD ID / OPT / IND ENABLING · PHASE 1A · PHASE 1B · PHASE 2A
CMTX-101	Anti-**DNABII** mAb (Infusion)	**Cystic Fibrosis** Expansion: NTM & NCFB	Interim analysis expected mid-2025
CMTX-101	Anti-**DNABII** mAb (Infusion)	**Pneumonia**	Phase 1b study completed 3Q24 with positive TLD
CMTX-301	Vaccine vs **DNABII** (IM Injection)	TBD	Supported with CARB-X funding

Pathogen-Agnostic Effect

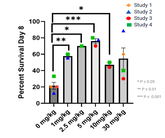
- Platform has demonstrated activity against **all key respiratory and ESKAPEE pathogens**[5]
- **Sensitizes pathogens to today's most commonly employed antibiotics**
- Opportunity to improve patient outcomes by improving antibiotic efficacy to clear infections more quickly, reduce need for polypharmacy

BIOFILM	ACTIVITY	ANTIBIOTIC SENSITIZATION
Nontypeable *Haemophilus influenzae*	✓	ceftazidime; clarithromycin; sulfamethoxazole/trimethoprim
Streptococcus pneumoniae	✓	levofloxacin; vancomycin; sulfamethoxazole/trimethoprim
Burkholderia cenocepacia	✓	ceftazidime; levofloxacin; sulfamethoxazole/trimethoprim
Enterococcus faecium	✓	ceftazidime; imipenem; vancomycin
Staphylococcus aureus (MRSA, MSSA)	✓	levofloxacin; linezolid; vancomycin
Klebsiella pneumoniae	✓	amikacin; ceftazidime; levofloxacin;
Acinetobacter baumannii	✓	colistin; levofloxacin; tobramycin
Pseudomonas aeruginosa	✓	ceftazidime; piperacillin; tobramycin;
Enterobacter spp.	✓	imipenem; levofloxacin; tobramycin
Escherichia coli	✓	ceftazidime; levofloxacin; sulfamethoxazole/trimethoprim
Mycobacterium avium, M. abscessus	✓	amikacin; azithromycin

Survival Benefit in Model of *P. aeruginosa*

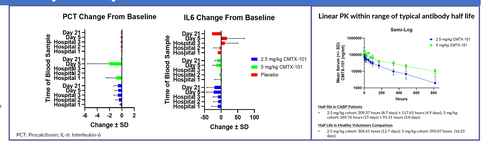
- Four separate murine pulmonary infection mortality studies showed consistent significant survival benefit of CMTX-101[7]
- Dose response (increased survival) observed across four studies from 1 to 5 mg/kg

Therapeutic Model: intranasal *Pseudomonas aeruginosa* bacterial challenge on Day 0, followed by single administration of CMTX-101 24 hours post-infection. Mean & Standard Error of the mean plotted. Untreated infection control (0 mg/kg) consistent across 4 studies; model established with 20% target survival for this group. Apparent prozone effect at CMTX-101 concentrations >5 mg/kg.



Impact in Community-Acquired Pneumonia

- Phase 1 trial in bacterial pneumonia supported scientific hypothesis[6]
- Change from baseline of PCT, IL-6 and CRP, in individual patients
  - Shortening the course of antibiotic therapy
  - Indicating therapeutic response
  - Supporting early clinical response or early clinical stability determination



Phase 2 Trial in Cystic Fibrosis Associated Infections

Interim data by mid-2025

Phase 1b	Phase 2a			Full Study
Part 1: Safety Escalation	**Part 2: Dose Finding**			
6 Subjects Dose escalation 5-30 mg/kg	**15 Subjects** 2:2:1 randomization Dose at 5 or 30 mg/kg	**Interim Analysis (IA)**	**20 Subjects** 2:2:1 randomization Dose levels TBD based on IA data	**41 Subjects** 34 CMTX-101 7 Control
Dosing Complete	Dosing Complete	In process, June completion		Clear Go/No-Go to Phase 2b+

Evaluation of Safety, Tolerability, PK, and Sputum Microbiological Endpoints

Primary Endpoints:	**Safety and tolerability**	
Secondary Endpoints:	**Characterization of the PK profile of CMTX-101** **Proportion of participants with antidrug antibodies and neutralizing antibodies** **Reduction in pulmonary *P. aeruginosa* bacterial burden**	
Exploratory Endpoints:	Reduction in pulmonary total bacterial burden Improvement in ppFEV1, LCI Laboratory values associated with liver and kidney function	CFQ-R Respiratory score Increase in body weight Changes in inflammatory biomarkers in sputum

RIS Respiratory Innovation Summit

ATS 2025 May 16-17 San Francisco

1. Kolpen M, et al. Bacterial biofilms predominate in both acute and chronic human lung infections. Thorax. 2. Fennelly et al. Am J Respir Crit Care Med. 193(6):692-3 (2016). 3. Goodman SD et al. (2011) https://doi.org/10.1038/mi.2011.27. Kurbatfinski et al. (2022) https://doi.org/10.1128/AAC.01877-21. 4. Brockson et al (2014) https://doi.org/10.1111/mmi.12735. Devaraj et al. (2018). 5. NCH Report_Antibiotic Senstization_Bakaletz, Clarametyx_2020-04, 06, 07; 2021-01, 02, 04; 2023-08; IBT-4503; NCH_Bakaletz_HumAbs OM model_colleague study; https://doi.org/10.1002/mbo3.563. 6. Presentation at IDWeek 2024. 7. Clarametyx, unpublished data.