

LTX-109 – a high value game changer in Diabetic Foot Infections

BIO San Diego 2014

A significant opportunity in Diabetic Foot Infections (DFI)

Several hundred million USD potential (DRG Research, June 2014)

- Large number of patients
 - ~2.3 million cases of DFIs in the G7 annually
- KOLs - preferred topical treatment option
 - Lower potential for resistance vs. systemic antibiotics
 - Topical formulation with improved safety
 - Potential convenience/compliance advantages – once daily dosing
 - Broad spectrum coverage
- Payers – indicated premium pricing could be obtained
 - Serious morbidity associated with DFIs
 - Acute nature of the condition
 - Topical advantages vs. existing systemic agents

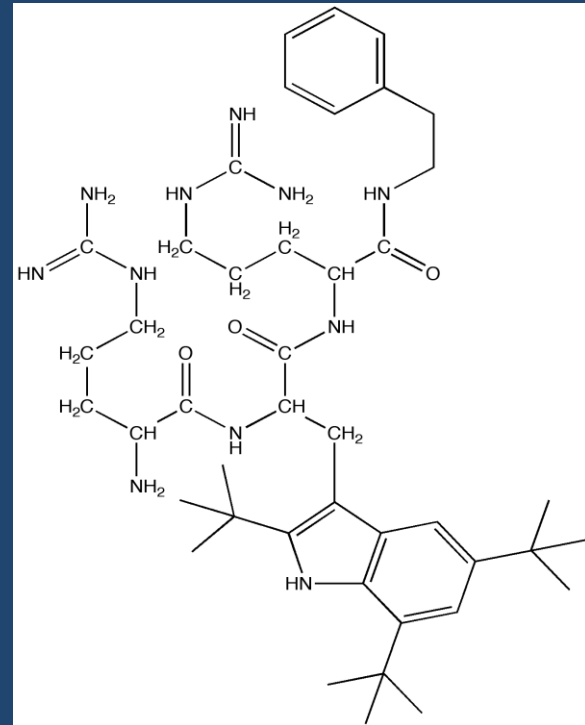
Lytix Biopharma AS

- Norwegian private company
- Technology based on mimetics of host-defense peptides
- Develops novel therapeutics for important unmet needs:
 - LTX- 315, treatment of Cancers, Phase I/II
 - LTX-109 treatment of topical infections Phase II

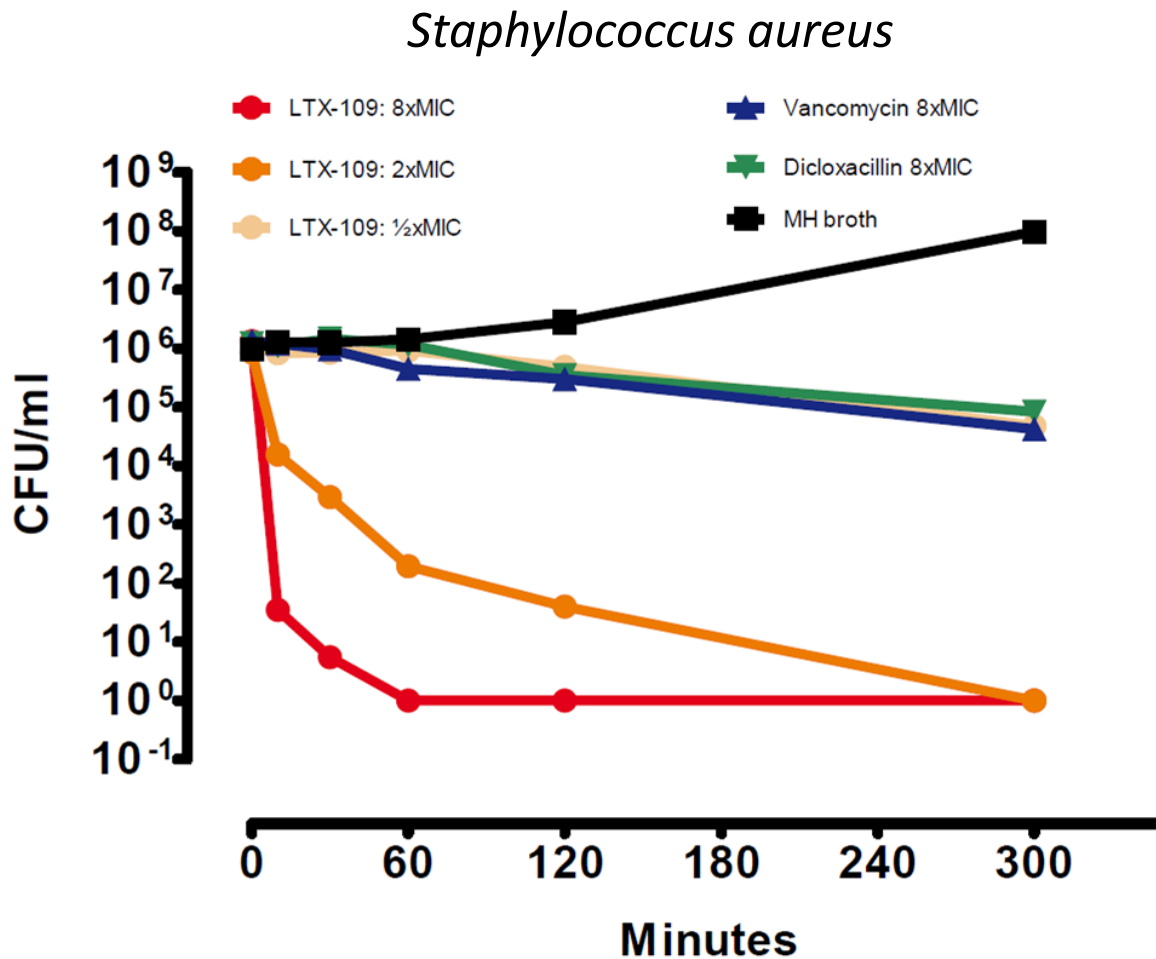


LTX-109 is a novel topical antimicrobial

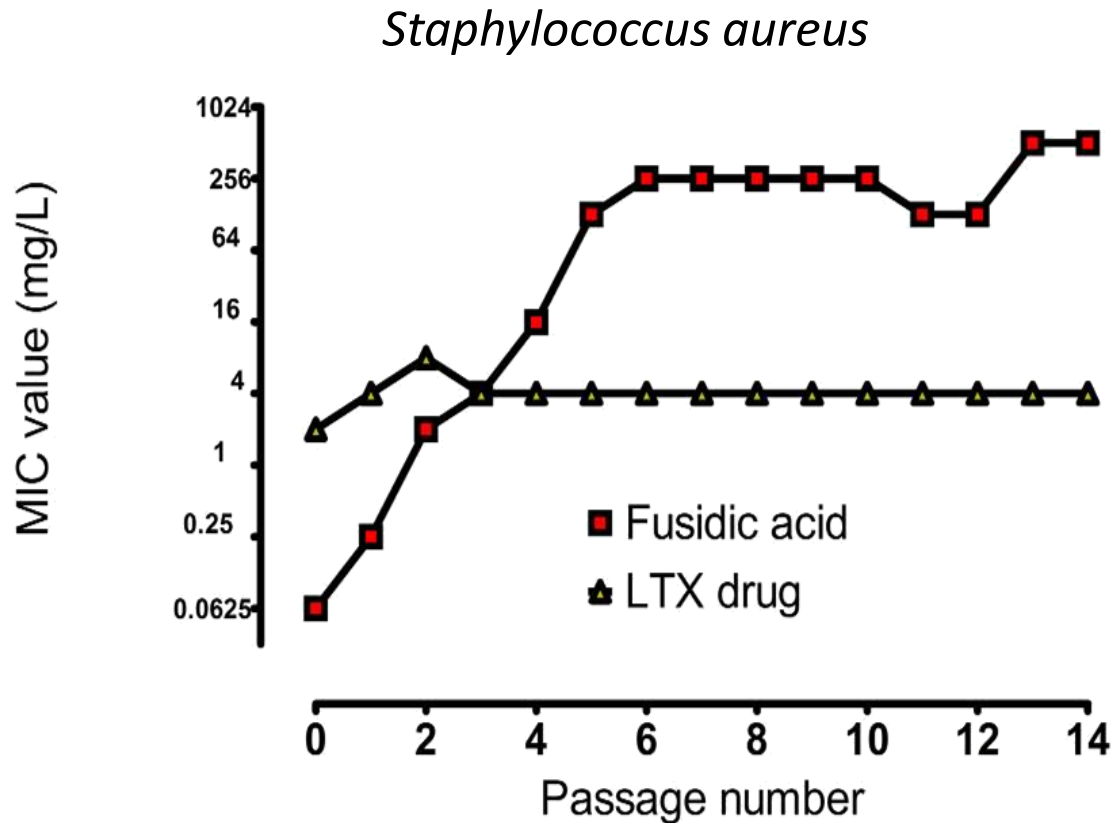
- Novel mode of action
- Rapid bactericidal effect
- Low propensity for resistance development
- Broad spectrum of activity
- Safe and well tolerated



LTX-109 is rapidly bactericidal



No resistance development observed



- Serial passage of *S. aureus* (Gram+) with 0.5x MIC of antibiotic in culture medium

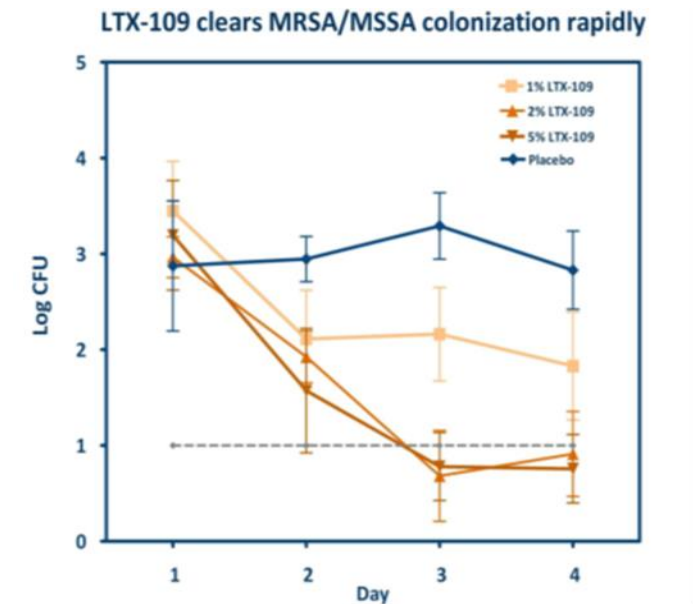
LTX-109 is a phase II clinical stage product

PoC for LTX-109 in impetigo

- 206 patients treated with LTX-109 (1%, 2% and placebo) TID for 5 days
- Clinical efficacy of LTX-109 measured at Day 4, Day 6 and Day 12
- Clinical success rate was higher for 1% and 2% LTX-109 than placebo/vehicle
- LTX-109 was safe and tolerable

Summary of clinical data

- LTX-109 is safe and tolerable
 - Safety data from ~300 subjects in 4 clinical trials
 - Doses: 1%, 2% and 5% LTX-109
- PoC in in nasal decolonisation
- PoC in impetigo



Unmet needs correspond with key features of LTX-109

**Antibacterial agents
with lower potential for
resistance**

“We have a major problem with systemic antibiotic with resistance, with side effects. Look at the WHO warning recently about overuse of antibiotics.” – DFI US KOL 2

“The doctors on the committee are very concerned about resistance. This is coming in from all physicians, the internists, paediatricians.” – US MCO PD 2

Topical treatment

“If you were able to treat mild infection with a topical, of course it would be better as systemic treatment has a huge number of side effects.” – DFI EU KOL 2

**Gram negative and
anaerobic bacteria
coverage**

“We don’t have a good solution for pseudomonas. I use generic gentamycin cream and I don’t find that works that well. Now there are some resistant species of Pseudomonas that are untreatable it means that topicals coming through will be the future.” – DFI US KOL 3

Significant commercial opportunity in DFI

- No topical antibiotic / antimicrobial approved in DFI
- Competitive risk from pipeline products is low / moderate
- 1,5 million cases of mild DFI in US/EU
- Several hundred million USD sales potential
- Additional opportunities: moderate DFI and other skin and skin structure infections

Comment from US KOL

*“These results should serve as a **stepping stone for further development** and study of LTX-109 for additional indications, such as infected diabetic foot ulcers.”*

Professor of Medicine, Benjamin A. Lipsky, MD, FACP, FIDSA, FRCP
(University of Washington, University of Geneva, University of Oxford)

Attractive licensing opportunity

Novel mode of action (stable peptide mimetic)	✓
Topical antimicrobial <ul style="list-style-type: none">• Low propensity for resistance• Broad spectrum activity• Safety advantages vs systemics	✓
PoC in Impetigo and Nasal Decol.	✓
Strong long lived IP	✓
Defined patient population in DFI	✓
High clinical unmet need	✓
Significant commercial opportunity	✓

We are actively seeking a partner for full licensing or co-development

Contact information

Håkan Wickholm
Director, Business Development
Lytix Biopharma AS
Gaustadalleen 21
NO-0349 Oslo, Norway



Mail: hakan.wickholm@lytixbiopharma.com

Mobile: +46 72 717 25 26