Lytix Biopharma X ...improving nature's own defense mechanisms

# LTX-109

August 2013

# Lytix Biopharma scientific background



#### Lactoferrin

Lactoferricin

- The lactoferrin protein is found in milk and is known to have direct anti-microbial activity and cancer immune modulatory effects
- Structure-activity-relationship studies have resulted in the design of two optimal molecules originating from the Company's technology platform; the anti-infective drug LTX-109 and the cancer immune therapeutic drug LTX-315

# Highly efficient peptides



- Host defence peptides form the cornerstone of the body's protection against a broad spectrum of harmful micro-organisms
- Some host defence peptides kill micro-organisms by direct disruption of the cell membrane (lysis). Such lytic peptides represent a novel class of drugs
- More recent research has shown that some host defence peptides have powerful anti-cancer effects. These peptides induce release of danger signals and tumor associated antigens (TAAs) from the tumor leading to protective immune responses

# Significant commercial potential for LTX-109

- Global sales of topical antibacterials estimated to USD 982m in 2010<sup>1</sup> (primarily Bactroban and Fucidin)
- Main product in market, Mupirocin, is used for skin infections and nasal decolonization
  - Total EU, US and JP sales 2012 of USD 190m<sup>2</sup>
  - As current treatment induces resistance, considerable potential is identified for increased sales in pre operative decolonization segment

- Bacterial resistance to antibiotics is a global and increasing problem
- Incidence of MRSA (meticillin-resistant *Staphylococcus aureus*) is increasing
  - Anticipated 20,000 deaths in the US due to MRSA
  - Compared to 10,000 deaths caused by HIV
  - Few novel antibiotics have been developed over the last decades

#### Rapid spread of antibiotic-resistant bacteria in the US



Source: Surveillance data from CDC (Centre for Disease Control, USA) – MRSA, methicillinresistant *Staphylococcus aures*; VRE, vancomycinresistant Enterococcus; FQRP, fluoroquinoloneresistant *Pseudomonas aeruginosa* ("Bad Bugs, No Drugs Whitepaper", IDSA 2004)

Source: Visiongain, 2012
IMS ex. Manufacturing sales 2012



# LTX-109 is a well-documented drug candidate

- ✓ Fast acting, bactericidal antimicrobial drug
- ✓ Broad spectrum of activity
- Low propensity for resistance development
- Effective against multi-drug resistant bacteria
- ✓ Effective against biofilms





#### In-vivo animal studies: LTX-109 kills MRSA better than Gold Standard drugs



- Murine skin infection model (tape-stripping, ATCC 33591)
- Read-out is bacterial growth +9 hours after the first of 3 doses

## Project status LTX-109

- ✓ Phase I in healthy volunteers completed
- ✓ Phase I/IIa pilot study in Gram+ skin infections completed
- ✓ Phase I/IIa pilot study nasal decolonisation completed

#### *Focus in 2013 and 2014*

- Phase II PoC in impetigo
- Active dialog with potential partners



# Impetigo – «milk blotch» in children

- Impetigo
  - Staphylococcus aureus and Streptococcus pyogenes
  - Pediatric disease
  - Incidence in 2-4 years old children
    - ~3 % UK
    - 12-25% in warmer humid climates
- Medical need
  - Increasing resistance to excisiting antibiotics (Fucidin and Bactroban)
  - Convenience of shorter treatment regimen

### Nasal decolonisation

- Medical need
  - Staphylococcus aureus are prevalent colonisers and the most common cause of hospital infections
  - MRSA (methicillin-resistant *S. aureus*) has become endemic in health care institutions worldwide, with up to 70% of invasive *S. aureus* infections having resistance
  - Short-term presurgical eradication of MRSA carriage:
    - Prevention of infection
    - Prevention of transmission

LTX-109 has the potental of effectively prevent S. aureus infections without succumbing to bacterial resistance



LTX-109 clears MRSA/MSSA colonization rapidly



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## LTX-109 development milestones

LTX-109	2010	2011	2012	2013	2014	2015
have at the						
Impetigo	Phas	e I/IIa pilot	Juvenile Tox	Phase II	ΡοϹ	
Nasal decolonisation	Phase	e I/lla pilot Re	e-formulation Re	g. adv		

- Phase II Proof of Concept study in impetigo is ongoing. Results expected first half of 2014
- Discussions with potential partners in the area of dermatology and topical infections are ongoing
- Effective killing of bacteria in the nose in a Phase I/IIa study. Results attracted great interest from leading clinicians in the field.
- Proof of Principle established in complicated wounds animal model



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