

# ALX-009

*A promising antimicrobial therapy for Cystic Fibrosis and Bronchiectasis*



**Member of iABC consortium**

**Program supported by**



# ABOUT ALAXIA

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- ▶ Founded in 2008, **ALAXIA** is a private SME biotech company located in Lyon (France), member of LyonBiopole
- ▶ Affiliate of **STRAGEN PHARMA** since 2011
- ▶ Main focus:  
Development of ALX-009 targeting respiratory diseases based on our peroxidase platform

1<sup>st</sup> Product:

**ALX-009**

OSCN-/Lactoferrin

# NEW DRUG DEVELOPMENT - 2 ORIGINAL MOLECULES

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*STRAGEN New Drug Development identifies promising patented compounds from biotechnology start-ups as well as academic institutions and develops these into drugs of high therapeutic potential.*

## **ALX-009 - CYSTIC FIBROSIS AND BRONCHIECTASIS**

An innovative first-in-class orphan drug combination of two endogenous substances.

## **STR-324 – PAIN**

A first-in-class non-opioid painkiller with a safe, non-addictive and innovative mode of action.

# ALX-009, A FIRST IN CLASS ANTIMICROBIAL DRUG CANDIDATE (1/2)

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- Innovative concept and program supported by BPI France, Cystic Fibrosis Foundation (USA) and member of iABC consortium, Innovative Medicines Initiative (EU)
  - *Association of 2 endogenous substances (OSCN/Lactoferrin) with antimicrobial properties mimicking the innate immune system → symptomatic treatment of lung infections via a solution for inhalation*
- ALX-009 is designated Orphan Drug Status by EMA and FDA in CF
- ALX-009 targets antibiotic-multiresistant Gram(-) bacteria that are not killed by current antimicrobials; the so called “bad bugs”
  - First target population in western countries : Cystic Fibrosis due to unmet medical need
  - Second target, Global : Bronchiectasis with partner

# ALX-009, A FIRST IN CLASS ANTIMICROBIAL DRUG CANDIDATE (2/2)

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- Multi-target mode of action limiting emergence of resistance:
  - OSCN: non specific oxidant of thiol groups,
  - LF: bacteriostatic
- Bactericidal effect maintained in complex matrices (biofilm and sputum) without requiring significant product dose increase
- Standalone therapy &/or adjunctive to antibiotics
- Phase I ongoing (for CF and BE indications)

# EFFICACY : BACTERIAL STRAINS SUSCEPTIBILITY\* TO ALX-009

Bacteria		Number of isolates Susceptible/Tested
Gram <sup>-</sup>	<i>Achromobacter spp.</i>	113/113
	<i>Burkholderia spp.</i>	186/186
	<i>Cupriavidus spp.</i>	3/3
	<i>Haemophilus influenzae</i>	5/5
	<i>Prevotella spp</i>	5/5
	<i>P. aeruginosa</i>	53/53
	<i>P. aeruginosa MDR</i>	46/46
	<i>Ralstonia spp.</i>	5/5
	<i>Stenotrophomonas maltophilia</i>	77/77
	<i>Yersinia pestis</i>	2/2
Gram <sup>+</sup>	<i>Bacillus spp.</i>	3/3
	<i>Streptococcus spp.</i>	4/4
	<i>Staphylococcus spp.</i>	4/9
	<i>S. aureus</i> MRSA	0/5

100% Efficacy demonstrated on Gram(-) of interest including antibiotic/multidrug resistant strains

\*defined by MIC microdilution method according to current CLSI conditions

# IABC

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- **Inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis (iABC)**
- Respiratory infections, frequently caused by Antibiotic Resistant bacteria, are the main cause of disease and death in people with cystic fibrosis (CF) and bronchiectasis (BE).
  - Thanks to inhaled antibiotics, patients now live longer than ever before and enjoy a better quality of life.
  - However, infections are increasingly becoming resistant to the few drugs available, putting patients' lives at risk.
- The iABC project is advancing the development of two inhaled antibiotics for patients with CF and BE. It is also working to identify ways of improving clinical trials of treatments for these serious diseases.
- iABC is a project belonging to IMI

NB : 33,000 deaths a year from resistant infections(All indications)

[https://ec.europa.eu/health/amr/antimicrobial-resistance\\_en](https://ec.europa.eu/health/amr/antimicrobial-resistance_en)

# IMI

- Innovative Medicines Initiatives (<https://www.imi.europa.eu/>)
- Public-private (EC/EFPIA) partnership funding health research and innovation
- IMI funding supports the participation in its projects of organisations like universities, SMEs research organisations, patient organisations,
- EFPIA companies do not receive any EU funding through IMI, but contribute to IMI through ‘in-kind’ contributions. These contributions are mostly in the form of:  
Personnel





# IABC

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- Project initiated by Novartis & Basilea
- Started in 2015 (Call in 2014) – Dec 2021
- Development of inhaled drugs
  - CMC, Preclinic, Clinical studies
- An IMI Project belonging to ND4BB program
  - EFPIA companies
  - **NOVARTIS** (~~TOBI~~ QBW251), ~~BASILEA~~, POLYPHOR (POL7080), ALAXIA (ALX-009)
  - Universities, research organisations, public bodies, non-profit groups
  - Belfast HSCT (UK), EUMC Rotterdam, NL, OMM Milan (It), HCL Lyon (Fr), INSERM (Fr), MH Hannover (DE), Papworth Hospital (UK), Rijksuniversiteit Groningen (NL), Royal Brompton (UK), SMS Madrid (Sp), U Edinburgh (UK), QUB Belfast (UK), U Milano (It), U Antwerpen (B), U Poitiers (Fr), UMC Utrecht (NL), U Dundee (UK), VHRI (Sp) VHUH (Sp)
- Total Budget 56 883 293 € (In Kind and In Cash)
- IMI Funding 24 331 609 € to Univ, Research... only.

# ALAXIA WITHIN IABC

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- Alaxia joined iABC in 2019 (Special Process)
  - Call for tender emitted by iABC (iABC project already accepted by IMI)
  - Preselection (Oct), Proposal (Nov), Selection (Feb), Entree (May)
  - Company must be a member of EFPIA
  - No funds to ALAXIA
- ALAXIA Interest ?
  - Network
    - Access to clinical centers and KOL
    - Access to patients
    - HCL collaboration
  - R&D done by iABC partners IMI sponsored
- Next ? (End of iABC, Dec 2021)
  - iABC 2

# TIP

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- TIP

- 1<sup>st</sup> EU project for Alaxia, 10 years after incorporation !
- We answered a lot of calls just after incorporation 2008 without any success\* and we decided to stop as too many competitors and too few winners (Prefer to spend time on our project, networking and on other sources)
- But always keep an eye on it and join networkS (iABC came from network)
- Thinks/Acts outside the box, avoid highways, look at small streets

\*keeping in mind, in our staff, we have skilled persons in EU project

# ALX-009

[www.alaxia-pharma.eu](http://www.alaxia-pharma.eu)

Member of iABC consortium

Program supported by



innovative  
medicines  
initiative



stragen<sup>+</sup>

bpi<sup>+</sup>france