

PRESS RELEASE

A disruptive technology to produce an innovative antimicrobial treatment for Cystic Fibrosis

Lyon (France), 24 January 2019 – A strategic milestone of the project ALX-009 has now been completed: Lyon-based biotech company Alaxia announces the start of production of its innovative device dedicated to the extemporaneous production of its drug candidate ALX-009. In an incredible timeframe, Alaxia has overcome the challenge of developing an intuitive and fully automated portable device. The production is now running since early January 2019. This innovative device was a must to give independent access to ALX-009 to patients, indeed it has been designed to allow full secure use by patients at home or by healthcare professionals. This will facilitate the pharmaceutical and clinical development of ALX-009.

A promising antimicrobial drug candidate

ALX-009 is a first-in-class orphan drug candidate developed to treat multi-drug-resistant bacterial lung infections in Cystic Fibrosis (CF) patients. The product is presented as a solution for inhalation.

ALX-009 corresponds to a fixed combination of two endogenous substances: hypothiocyanite and lactoferrin. Both substances are normally produced by the lungs in response to infection but are deficient in CF patients.

The efficacy of ALX-009 has been demonstrated on a wide range of multi-drug-resistant bacteria infecting the lungs of CF patients, including *Achromobacter xylosoxidans*, *Burkholderia spp.*, *Pseudomonas aeruginosa* and *Stenotrophomonas maltophilia*. In contrast to antibiotics, the drug candidate's antimicrobial efficacy, which mimics the innate immune response, is not reduced by complex matrices such as biofilms or the abundant mucus produced in the lungs of CF patients. In addition, its multi-target mode of action hampers the risk of generating antimicrobial resistance.

A unique production method

The high activity of the hypothiocyanite anion, conferring its strong bactericidal properties, requires extemporaneous production of the drug candidate ALX-009. To overcome this critical constraint, Alaxia has successfully completed the challenging development of a dedicated device for ALX-009 production. This device allows patients to self-operate the ALX-009 automated production. The ready-to-use ALX-009 solution is produced in 15 minutes. It can then be administered using a nebulizer.

The device is composed of two parts, one, a reusable part (= docking station) which pilots the operating steps occurring during ALX-009 production, and a sterile disposable part (= single-use cassette) which embeds a micro-dialysis module. The device works on a closed-circuit air circulation system avoiding the use of any pumps, preservatives or lubricants.

The device guarantees the production of a safe drug candidate as it includes built-in security functions to ensure an easy, reliable and safe production for administration to patients.

About Alaxia:

Alaxia is a French biotech company affiliated to Stragen Group and supported by BPI France and the US Cystic Fibrosis Foundation. Its aim is to address unmet medical needs in serious respiratory diseases through the development of therapeutic solutions based on its own proprietary peroxidase platform. ALX-009 is Alaxia's most advanced drug candidate.

For additional information, please visit www.alaxia-pharma.eu.

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