

PHAXIAM Therapeutics announces enrolment of the first patient in the phase 1 study for the treatment of endocarditis infections caused by *Staphylococcus aureus*

- The study plans for the enrolment of 12 patients in 5 French clinical centers
- First study results expected in Q3 2024
- This study will enable an evaluation of the intravenous administration of phages, particularly adapted to targeting indications with very high medical stakes

Lyon (France) and Cambridge (MA, US), April 15, 2024 – 7:30am CEST - PHAXIAM Therapeutics (Nasdaq & Euronext: FR0011471135), today announces the enrolment of the 1st patient in the phase 1 clinical study in endocarditis infection caused by *Staphylococcus aureus* (*S. aureus*).

Endocarditis is an infection of the endocardium (inner lining of the heart) and valves, usually caused by bacteria. It can lead to heart failure, valve damage and stroke. It remains one of the most fatal heart diseases, with a death rate from 30 to 40%. *S. aureus*, responsible for around 30%¹ of cases, is the main cause of endocarditis infections. Its treatment involves antibiotics, sometimes combined with surgery to repair damage to the heart valves. Given the increase in the incidence and mortality of endocarditis due to *S. aureus* in the context of growing antibiotic resistance, the development of innovative therapies has become a necessity to control and reduce the mortality rate of infectious endocarditis.

The design of PHAXIAM's multicentric phase 1 study in this indication received the necessary approvals from the French regulatory agency ANSM and Sud-Est II-Lyon Ethics committee. The trial plans to enroll 12 patients requiring replacement of an infected heart valve, recruited across 5 French clinical centers (Henri Mondor in Créteil, Hôpital Bichat-Claude Bernard in Paris, University Hospital of Nantes, University Hospital of Nancy and La Pitié-Salpêtrière in Paris).

The first patient has been enrolled at Henri Mondor Hospital by the team of Professor Pascal Lim, the study's Principal Investigator. Patients will be treated between 2 and 4 days with a combination of two anti-*S. aureus* phages, intravenously administered once or twice a day, until the day of surgery. The primary objective of the study is to assess the safety of intravenous administration of PHAXIAM's phages, to study their pharmacokinetics in the blood and to measure their concentration in the valve resected during surgery.

These key data for PHAXIAM and wider for the development of phage therapy will be used to define the optimal intravenous administration method and will also be used for future efficacy studies of phage therapy in indications using this administration pathway. The first results of the study are expected during the 3rd quarter of 2024.

Prof. Pascal Lim, Head of Cardiac Intensive Care at Hôpital Henri Mondor and Principal Investigator of the study, stated: *"The treatment of endocarditis infection linked to S. aureus presents many challenges, and we are very pleased to take part in this study, which will evaluate phage therapy for the first time in this highly fatal condition. In this way, we hope to contribute to improving the treatment of patients who often face a therapeutic impasse."*

¹ Selton-Suty C., Célarid M., Le Moing V., et al. Preeminence of *Staphylococcus aureus* in infective endocarditis: a 1-year population-based survey. *Clin Infect Dis* 2012; 54 : 1230-9.

Thibaut du Fayet, Chief Executive Officer of PHAXIAM, concluded: *"The inclusion of the first patient in the phase 1 study in endocarditis infection is a key step in our development strategy, which aims to provide phage therapy to patients suffering from diseases of high medical needs. The first results of this study, expected in Q3 2024, will enable us to analyse the safety and first efficacy signals of our anti-S. aureus phages with intravenous administration, in an indication where reducing mortality, which is still between 30% and 40%, is a major medical challenge. We look forward to these data, which, if positive, will give us a significant competitive advantage and will pave the way for the use of this administration route for our phages in other indications with significant unmet medical needs, such as bacteraemia."*

About PHAXIAM Therapeutics

PHAXIAM is a biopharmaceutical company developing innovative treatments for resistant bacterial infections, which are responsible for many serious infections. The company is building on an innovative approach based on the use of phages, natural bacterial-killing viruses. PHAXIAM is developing a portfolio of phages targeting 3 of the most resistant and dangerous bacteria, which together account for more than two-thirds of resistant hospital-acquired infections: Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa.

PHAXIAM is listed on the Euronext regulated market in Paris (ISIN code: FR0011471135, ticker: PHXM). PHAXIAM is part of the CAC Healthcare, CAC Pharma & Bio, CAC Mid & Small, CAC All Tradable, EnterNext PEA-PME 150 and Next Biotech indexes.

For more information, please visit www.phaxiam.com

Contacts

PHAXIAM
Eric Soyer
COO & CFO
+33 4 78 74 44 38
investors@phaxiam.com

NewCap
Mathilde Bohin / Dušan Orešanský
Investor Relations
Arthur Rouillé
Media Relations
+33 1 44 71 94 94
phaxiam@newcap.eu

Forward-looking information

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