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

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- **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."*

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

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Forward-looking information

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical programs, development plans, business and regulatory strategy and anticipated future performance of PHAXIAM and of the market in which it operates. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will” and “continue” and similar expressions. All statements contained in this press release other than statements of historical facts are forward-looking statements. Such statements, forecasts and estimates are based on various assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable when made but may or may not prove to be correct. Actual events are difficult to predict and may depend upon factors that are beyond PHAXIAM's control. Therefore, actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates. Investor should carefully read the risk factors section of the Company which can be found in the Company’s regulatory filings with the French Autorité des Marchés Financiers (AMF), including in the Company’s 2023 Universal Registration Document (Document d’Enregistrement Universel) filed with the AMF on April 5, 2024 and future filings and reports by the Company. Given these uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this press release. PHAXIAM disclaims any obligation to update any such forward-looking statement, forecast or estimates to reflect any change in PHAXIAM’s expectations with regard thereto, or any change in events, conditions or circumstances on which any such statement, forecast or estimate is based, except to the extent required by law.

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1 *Selton-Suty C., Célard 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.*

Attachment

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