PHAXIAM

PRESS RELEASE

PHAXIAM Therapeutics obtains authorizations to launch its phase 1 study in endocarditis infections caused by *Staphylococcus aureus*

- **Approval of study design by French ANSM and Ethics Committee**
- **Recruitment of 12 patients expected to start in Q4 2023 in 4 French centers**
- **First study results expected in mid-2024**

Lyon (France) et Cambridge (MA, US), October 24, 2023, at 10:05 pm CEST – PHAXIAM Therapeutics (Nasdaq & Euronext: PHXM), a biopharmaceutical company developing innovative treatments for resistant bacterial infections, announces the approval of its phase 1 study clinical design in endocarditis infections caused by *Staphylococcus aureus* (*S. aureus*) by the French National Agency for the Safety of Medicines and Health Products (ANSM) and the South-East II-Lyon Ethics Committee (*Comité de Protection des Personnes* - CPP).

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%. The main cause of endocarditis infections, *S. aureus*, is responsible for around 30%[1] of cases. Its treatment involves antibiotics, sometimes combined with surgery to repair damage to the heart valves. Despite advances in the prevention and treatment of other cardiovascular diseases, the incidence and mortality of endocarditis due to *S. aureus* increased in recent years, requiring the development of innovative therapies to tackle antimicrobial resistance.

The design of PHAXIAM's multicenter phase 1 study in this indication received the necessary approvals from the ANSM and Sud-Est II-Lyon Ethics committee. The trial plans to involve 12 patients requiring replacement of an infected heart valve. Recruited across 4 French hospitals (Henri Mondor in Créteil, Hôpital Bichat-Claude Bernard in Paris, University Hospital of Nantes and University Hospital of Nancy), patients will be treated between 2 and 4 days with a combination of 2 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 phages, to study their pharmacokinetics in the blood and to measure their concentration in the valve resected during surgery.

These data will be used to define the optimal intravenous administration schedule and will also be used for future phage therapy efficacy studies in indications requiring this administration route. The first results of the study are expected in mid-2024.

Pascal Birman, Chief Medical Officer of PHAXIAM Therapeutics, stated: *"This phase 1 study was designed primarily to assess the safety and pharmacokinetics of our anti-S. aureus phages in the treatment of endocarditis infections. It also aims to validate the intravenous administration route, likely to improve patient exposure to our phages. Subject to positive data, we could use this administration method in subsequent efficacy studies on larger patient populations and in other clinical indications associated with a strong unmet medical need, such as bacteremia."*

Thibaut du Fayet, Chief Executive Officer of PHAXIAM Therapeutics, concluded: "*These approvals enable us to take a major step forward in our most strategic S. aureus program, by positioning ourselves in a second, high value-added indication. With this new clinical trial, we are reaffirming our ambition to position phage therapy in indications with high unmet medical needs, where reducing patient mortality is a critical issue. The treatment of endocarditis infections caused by S. aureus using phage therapy could thus offer a major alternative and hope to many patients who have reached a therapeutic impasse."*

[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.*

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 Nasdaq Capital Market in the United States (ticker: PHXM) and 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

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. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, the following: (1) the inability to maintain the listing of PHAXIAM’s shares on the Nasdaq Capital Market and the Euronext regulated market; (2) changes in applicable laws or regulations; (3) the possibility that PHAXIAM may be adversely affected by other economic, business and/or competitive factors; and (4) other risks and uncertainties indicated from time to time in PHAXIAM’s regulatory filings. Further description of these risks, uncertainties and other risks can be found in the Company’s regulatory filings with the French Autorité des Marchés Financiers (AMF), the Company’s Securities and Exchange Commission (SEC) filings and reports, including in the Company’s 2022 Universal Registration Document (Document d’Enregistrement Universel) filed with the AMF on March 28, 2023 and in the Company’s Annual Report on Form 20-F filed with the SEC on March 28, 2023 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. Readers are cautioned not to place undue reliance on any of these forward-looking statements. 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.