PHAXIAM Therapeutics announces the validation of a new investigator-initiated phase 2 study

Oct 09, 2024 | Press Releases

- **A Phase 2 study sponsored by Assistance Publique – Hôpitaux de Paris (AP-HP) as part of the hospital-based clinical research program (PHRC)**
- **Evaluation of the efficacy of a local treatment with PHAXIAM's anti-*S. aureus* phages added to the standard treatment by surgery and antibiotics**
- **80 patients to be enrolled in 27 French clinical centers**
- **Validation of the study protocol by the ANSM expected in H1 2025**

Lyon (France), October 9, 2024 – 06:00pm CEST - PHAXIAM Therapeutics (Euronext: PHXM - FR0011471135), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, today announces the validation, as part of the French Hospital Clinical Research Program (PHRC), of a new Instigator-sponsored trial (IST), PHAGOSCARPA, in extra-cavitary vascular grafts implant infections caused by *Staphylococcus aureus (S. aureus)*.

The number of vascular prostheses is increasing every year and vascular graft infection occurs in 1-5% of patients. *Staphylococcus aureus* is the most common bacterium involved (20-53%) in extra-cavitary (EC) vascular graft infection (VGI). The mortality rate is very high and estimated at 10-25% within 30 days after diagnosis and over 50% after 1 year. The risk of amputation ranges from 4 to 14%. These infections are difficult to eradicate due to biofilm formation and increasing antimicrobial resistance. The standard of care (SoC) includes surgical detersion of the surgical site and vascular graft with prolonged antibiotic treatment. VGI are difficult and costly to treat, despite advances in antibiotic management and new operative techniques.

Satisfactory results have been obtained for the compassionate clinical use of PHAXIAM's phage therapy for vascular graft infection when conventional treatment has failed. Lytic phages, unaffected by resistance to anti-*S. aureus* antibiotics, can be used in combination with antibiotics and have a rapid bactericidal and synergistic action against biofilm. Phage tolerance was good, with no signs of local or systemic toxicity, in clinical case series.

Based on these promising results, PHAGOSCARPA was designed as a multicentric, randomized and blinded phase 2 study to evaluate the efficacy of PHAXIAM's anti- *S. aureus* phages administered locally vs. SoC.

The primary endpoint consists in the therapeutic success rate at 3 months, including:

- absence of clinical signs of infection (T°C≤38.0°C; no local inflammation),
- normal graft function (no infection-related bleeding, ischemia distal, major amputation),
- absence of radiological evidence of infection on CT, with no other explanatory causes identified.

Sponsored by Assistance Publique – Hôpitaux de Paris (AP-HP), the study received the approval from the Hospital Clinical Research Program and the Scientific Council of the National Network for Clinical Research in Infectious Diseases. The study plans to enrol 80 patients, recruited across 27 French clinical centers. The inclusion period is estimated at 24 months, with a patient follow-up for a further 12 months, i.e. an overall study duration of 36 months. The launch of the study is subject to validation of its clinical protocol by the French health authority (ANSM), expected in the first half of 2025. PHAXIAM is committed to ensuring the supply of the clinical doses required for the conduct of the study and will negotiate with the sponsor for access to the clinical data generated by this phase 2 trial.

Sylvain Diamantis, MD, Head of the Infectious and Tropical Diseases Department at Melun Hospital and Principal Investigator of the study, stated: *"We are very pleased with the work carried out in preparation for this study involving 27 French clinical centers and targeting a severe resistant infection. The number of vascular graft implants increases every year and Staphylococcus aureus is the most common bacterium involved in case of graft infection. We think that the use of phage therapy in combination with standard treatment could contribute to improve the treatment of patients who often face a therapeutic impasse, and we are thrilled to start this new trial."*

Pascal Birman, MD, Chief Medical Officer of PHAXIAM, concluded: *"This validation of a new investigational-sponsored trial, based on the data from compassionate treatments, once again reflects the added value that phage therapy could bring to the treatment of severe and resistant bacterial infections. We are proud to support the AP-HP in this study by providing clinical batches of our anti-S. aureus phages which have already shown promising results in compassionate use. We look forward to starting as soon as possible the enrolment in this new indication with high unmet medical needs."*

As a reminder, two other investigator-sponsored trials, in which PHAXIAM is involved, are also planned in high-value indications:

- Phase 2 study (60 patients) in Diabetic Foot Ulcer (DFU) sponsored by Nîmes Hospital (France), targeting DFU infections due to mono-bacterial *S. aureus* infection and ready for First Patient-In, expected before the end of 2024.
- Phase 2 study (180 patients) targeting nosocomial pulmonary infections due to *P. aeruginosa*, sponsored by La Pitié Salpêtrière Hospital in Paris (France), including patients with ventilator-associated pneumopathies (VAP). The filing of this study is planned in France (ANSM) in Q1 2025.

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.

Attachment

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