PHAXIAM Therapeutics Receives FDA Clearance to Initiate Phase II GLORIA Study in the U.S.

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- **GLORIA, the world's 1st phase II phage therapy study in the treatment of Prosthetic Joint Infections (PJI) related to Staphylococcus *aureus***
- **The clinical protocol also being submitted to the European health authorities and the MHRA in the UK**
- **Patients recruitment scheduled to start in Q1 2025 for clinical data readout expected in Q3 2026**

Lyon (France), November 04, 2024 – 6:00 pm CET - PHAXIAM Therapeutics (Euronext: PHXM - FR0011471135), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, announces that it has received *Investigational New Drug* approval (IND) for its Phase II study, GLORIA, in Prosthetic Joint Infections (PJI) caused by *Staphylococcus aureus* (*S. aureus*).

The GLORIA study is PHAXIAM's most strategic asset, with the highest priority. This study will be the 1st worldwide (Europe and United States) multicenter, randomized, placebo-controlled, proof-of-concept study in phage therapy and in PJI. The study plans to include 100 patients with PJI (hip or knee replacement) with open surgical debridement (DAIR), who will be treated with PHAXIAM's *anti-S. aureus* phages or placebo, in combination with antibiotics.

Prosthetic Joint Infection (PJI) is a severe complication that affects thousands of patients who have received hip or knee replacements, with 50-60,000 new cases per year in Western countries[1]. The unmet medical need is considerable insofar as current standards of care show a failure rate of 50%, with high risks of reinfection (60%), amputation (11%) and mortality (25% at five years). In addition, treatment costs are high and represent a heavy burden on health systems. In the United States, the incidence of patients is threefold the European patients' incidence, considering in addition a pricing gap of 25-30% for the treatment. PJI US market for *anti-S. aureus* phages is estimated at €600-700 million[2].

Phage therapy represents a promising solution in this context and PHAXIAM benefits from a leadership position in this indication. This status is supported by robust clinical data from several dozen patients treated in real-life compassionate setting with locally administered anti-S. *aureus* phages, which confers to the treatment a very good safety profile and already showed clinical benefits.

The IND approval received from the FDA on the GLORIA study protocol is a major step forward in the deployment of PHAXIAM's international clinical strategy. The company has already identified 5 clinical centers and intends to reach 10 participating centers to ensure a territorial network coverage to optimize the recruitment of the study.

Based on the structuring exchanges with the FDA, PHAXIAM is also about to finalize the filing of the clinical protocol with the main European health authorities[3], including the British MHRA. Subject to these approvals, the GLORIA study will be conducted in 7 European countries (France, Germany, UK, Spain, Italy, Netherlands, Sweden) and the United States, making it the most robust phage therapy study in the world.

Professor Tristan Ferry, coordinator of the Reference Center for Complex Osteoarticular Infections (CRIOAC) at the Croix-Rousse Hospital (HCL, Lyon) and internationally recognized expert in phage therapy, will be the principal investigator of the study.

Subject to the successful completion of GLORIA, expected in Q3 2026, PHAXIAM could be eligible for an early access process and could look for getting Conditional Market Approval (CMA), paving the way for pre-commercialization in Europe as early as the second half of 2027.

Thibaut du Fayet, Chief Executive Officer of PHAXIAM Therapeutics, said: *"This FDA IND clearance is a major recognition of our therapeutic approach and of our whole platform. This is a key milestone in our most strategic S. aureus program, and I would like to thank all our teams who have contributed to it. This is the first time that PHAXIAM will be in a position to conduct clinical development in the United States, and we look forward to moving ahead in the collaboration with the participating centers already identified. In parallel, we are finalizing the submission of the GLORIA protocol to the European authorities, with the aim of obtaining authorizations in seven countries of the European Union and the United Kingdom in the coming weeks. The confirmed objective remains to be able to start the recruitment of this first global study in phage therapy during the 1st quarter of 2025, as initially planned. With these strategic advances, we are about to reinforce our position as a leader in phage therapy for Prosthetic Joint Infection, a critical indication with high worldwide incidence and critical unmet medical needs. The GLORIA study may be the first global study to deliver a robust (with 100 patients enrolled) clinical proof-of-concept for phages. We consider that relying on the large PJI compassionate clinical data package, already generated in real life, the likelihood of success of this trial is rather high. We remain determined to provide a major solution and hope to many patients in a therapeutic impasse."*

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] *Europe 27 and the United States*

[2] *Source: internal evaluation by the Company*

[3] *A CTA (Clinical Trial Approval) application will be filed to be able to conduct the study in the 5 main European countries (France, Germany, Italy, Spain and the United Kingdom), as well as in Sweden and the Netherlands.*

Attachment

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