PHAXIAM

PRESS RELEASE

PHAXIAM Therapeutics presents clinical data of the PhagoDAIR pilot study, with results confirming the design of the GLORIA Phase II clinical study

- **This non-comparative[1] pilot study, including patients with Prosthetic Joint Infections (PJI), recruited 29 patients, 26 of whom were evaluable for clinical activity, out of the 64 initially planned, due to overly restrictive inclusion criteria**
- **Clinical data obtained in the "Phages" experimental arm (n=19), from patients who received a single intra-articular injection:**
  1) confirm the safety of PHAXIAM's anti-*Staphylococcus aureus* (S. *aureus*) phages,
  2) demonstrate an infection control rate of 74% (14/19) and are very consistent with data observed in compassionate treatments.
- **Clinical data from 2 of the 4 relapsed patients (3 in the "Phages" arm, 1 in the placebo arm) who benefited from rescue medication, demonstrated infection control at 12 weeks, after receiving 3 intra-articular injections of phages**
- **The overall rate of infection control, combining initial treatment and patients having a rescue medication after relapse, with 1 or 3 administrations injections, is still increased to 80%** (16/20)
- **PHAXIAM is now focusing on the GLORIA Phase II study, which will enroll 100 patients in Europe and the United States from Q1 2025 onwards, using expanded criteria compared with PhagoDAIR, and which aims to provide robust proof-of-concept of the clinical benefit of its anti-*S. aureus* phages in PJI after 3 injections of phages**

Lyon (France) – December 30, 2024, at 5:45 p.m. CET – PHAXIAM Therapeutics (Euronext: PHXM - FR0011471135), a biopharmaceutical company developing innovative treatments for severe and resistant bacterial infections, today announced the clinical results of the PhagoDAIR I pilot study, demonstrating an excellent phage safety profile and a 74% infection control rate in the Phages arm for patients who received a single intra-articular injection, consistent with clinical data that observed in patients treated on a compassionate basis. Given the small number of patients in the placebo arm, and the unbalanced randomization of patients between the two arms, analysis of the study's primary objective remains difficult to interpret, notably in the placebo arm.

Encouraging Clinical results of PhagoDAIR I pilot study and very consistent with generated compassionate clinical data

The PhagoDAIR study is a randomized, multicenter, **non-comparative**, double-blind pilot study in patients with *S. aureus* infection of hip or knee prostheses (PJI) occurring more than one month after prosthesis insertion, with an indication for suppressive antibiotic therapy. The study initially planned to include 64 patients, but due to overly restrictive selection criteria, only 29 patients were randomized, 26 of whom were evaluable for clinical activity.

The randomization of the 29 patients was unbalanced, with 20 patients in the "Phages" arm and only 9 in the placebo arm. Stratification by center and prosthesis location, combined with small numbers and many clinical centers having recruited only one or two patients, explain this imbalance, making it difficult to analyze the study's primary objective in the placebo arm.

All patients were treated with the standard of care (DAIR - debridement, antibiotic therapy and prosthesis maintenance), and randomized between the experimental "Phages" arm, treated with phage therapy

[1] no statistical comparison per protocol.

(n=19) and the control arm receiving a placebo (n=7). Phage-treated patients received anti-*S. aureus* phages active on their strain (1 intra-articular injection), selected using PHAXIAM's phagogram. The primary endpoint was the percentage of patients in each treatment arm free of infectious relapse at 12 weeks (infection control rate). This infection control analysis was combined with a safety analysis, assessing adverse events, in each of the two treatment arms.

Tolerance analysis of the 29 randomized patients confirmed the safety of phages, which had already been noted at the biannual Data Safety Monitoring Board (DSMB) meetings, which recommended continuation of the study.

Of the 26 evaluable patients (19 in the "Phages" arm and 7 in the placebo arm), 14/19 (74%) had a positive infection control rate in the "Phages" arm and 5/7 (71%) in the placebo arm, in which the antibiotics were administered alone. In the "Phages" arm, the infection control rate at 12 weeks remains very consistent and equivalent to that recently observed in patients treated with phages under compassionate status, estimated at around 75% for a population of around 60 patients. PHAXIAM also plans to publish updated real-life data from around 90 European patients treated with PHAXIAM phages under compassionate status.

Among the 7 relapsed patients, 4 patients (3 in the "Phages" arm, 1 in the placebo arm) benefited from a rescue medication, consisting of a weekly administration of phages for 3 consecutive weeks. Among these 4 patients, 2 did not relapse within 3 months of phage administration.

The consolidated infection control rate, including patients for whom phages were administered during DAIR or after a subsequent relapse leading to a rescue medication, with 1 or 3 administrations, was 80% (16/20). These encouraging results validate the decision to follow the same treatment regimen in the GLORIA Phase II study and confirm the relevance of launching this clinical trial.

Focus on the GLORIA Phase II study, the 1st global phage therapy study

The GLORIA study is PHAXIAM's most strategic and priority asset. It is the first global, multicenter, randomized, placebo-controlled proof-of-concept phage therapy study in PJI, conducted in Europe and the United States. The study plans to include 100 patients with PJI (hip or knee prosthesis) with an indication for open surgical debridement (DAIR), regardless of the time lapse between prosthesis placement and the onset of *S. aureus* infection; patients will be treated with PHAXIAM anti-*S. aureus* phages with three intra-articular injections or placebo, in combination with 12-week curative antibiotic therapy, without suppressive antibiotic therapy.

This clinical study will thus benefit from all the preparatory work carried out in PhagoDAIR study, including in particular knowledge of the clinical environment and clinical data, maximizing the probability of success of the proof-of-concept demonstration and better controlling patient inclusion, because: (1) the exclusion/inclusion criteria are different, making it possible to target a population circa six to seven times larger, including patients from all DAIR indications and without prior suppressive antibiotic therapy, unlike the PhagoDAIR study; (2) defined statistical methodology makes it possible to limit the complexities of randomization. The PhagoDAIR pilot study has thus enabled PHAXIAM to prepare and structure the GLORIA comparative clinical study, which will be launched in Q1 2025.

Regarding the protocol of this study, PHAXIAM has received IND approval from the US FDA in Q4 2024; the Company has also submitted the clinical protocol to the main European health authorities[2], including the MHRA in the United Kingdom. Subject to these approvals, the GLORIA study will be conducted from Q1 2025 in 7 European countries (France, Germany, United Kingdom, Spain, Italy, Netherlands, Sweden) and in the United States, making it the most robust phage therapy study in the world.

[2] A CTA (Clinical Trial Approval) application has been filed to conduct the study in the 5 main European countries (France, Germany, Italy, Spain and the UK), as well as in Sweden and the Netherlands.

Pascal Birman, PHAXIAM's Chief Medical Officer, stated: "*We are pleased that this study confirms the good tolerance of intra-articular administration of phages, and that the rate of infection control in the "Phages" arm is very consistent with all the clinical data generated in real life, and that, combining initial treatment and patients having a rescue medication after relapse, the overall rate of infection control reaches 80%. We are convinced that the GLORIA study, which has obtained FDA approval and is currently being reviewed in Europe, will enable us to avoid the difficulty of inclusion and the complexity of patient randomization, by targeting a much larger population and using a more appropriate statistical methodology. On the strength of these valuable insights, we are now accelerating our clinical development strategy in this indication, through our GLORIA Phase II study, which should start enrollment in Q1 2025, as planned*."

Pr. Tristan Ferry, Coordinator of the Referral Center for the Management of Complex Bone and Joint Infection (CRIOAC) at *Hôpital de la Croix-Rousse* (HCL, Lyon), adds: *"The clinical data from PhagoDAIR I are encouraging and validate the clinical interest of phages and the methodological choices made for GLORIA, both from the "Phages" arm, whose clinical activity (~75%) is very consistent with real-life data from compassionate treatments, and from the 4 relapsed patients who received rescue medication, 2 of whom did not relapse again within 3 months of phage administration."*

About PhagoDAIR study

The PhagoDAIR I study is a pilot, randomized, multicenter, non-comparative, double-blind study in patients with hip or knee prosthesis infection due to Staphylococcus aureus (SA), occurring more than one month after prosthesis insertion. All patients were treated with DAIR (debridement, antibiotic therapy and prosthesis retention). Curative antibiotic therapy for 12 weeks is followed by prolonged suppressive antibiotic therapy. Patients were randomized to receive, in addition to intra-articular DAIR, either one or both anti-Staphylococcus aureus phages, depending on the phagogram result, or placebo.

The primary endpoint at 12 weeks was the percentage of patients in each treatment arm free of infectious relapse. Infectious relapse is defined by the presence of clinical signs of active infection and/or the presence of Staphylococcus aureus in joint fluid. Patients in infectious relapse, regardless of their treatment arm, may receive a rescue medication consisting of weekly intra-articular administration, under ultrasound control, of one or both anti-Staphylococcus aureus phages, depending on the phagogram, for 3 consecutive weeks.

This analysis of infection control at 3 months is combined with a safety analysis (evaluation of adverse events, routine biology and inflammatory markers) in each of the 2 treatment arms.

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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Forecast 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.