



Pherecydes Pharma Has Submitted An Application For The Approval Of A Phase I Clinical Study In Infective Endocarditis Caused By *Staphylococcus Aureus*

The study should include 12 patients,
and its launch is expected in the third quarter of 2023

Nantes, June 8, 2023 – 7.30 am CEST - Pherecydes Pharma (FR0011651694 - ALPHE), a biotechnology company specializing in precision phage therapy to treat resistant and/or complicated bacterial infections, today announces that it has submitted an application for the approval of a phase I clinical study in infective endocarditis caused by *Staphylococcus aureus* (*S. aureus*) with the ANSM (the French National Agency for the Safety of Medicines).

Endocarditis is an infection of the endocardium (inner layer of the heart) and heart valves most often caused by bacteria. In developed countries, *S. aureus* is the primary cause, accounting for almost 30% of cases¹. Patients are systematically hospitalized, treatment is very complex and therapeutic alternatives are therefore necessary. Indeed, endocarditis requires heart surgery in 15% to 45% of cases and is fatal in 20% to 30% of hospitalized patients². It causes cardio-neurovascular complications such as strokes, embolization other than a stroke, heart failure and intracardiac abscesses despite intensive antibiotic therapy. Endocarditis due to *S. aureus* is even more serious than the other forms of infection, with a higher risk of death (>40%³) and a greater need for surgery to replace the valve at the acute stage of the disease.

The clinical protocol of the Pherecydes Pharma phase I study submitted to the ANSM foresees the enrollment of twelve patients in four clinical centers in France. Patients with native valve endocarditis caused by *S. aureus* requiring surgery to replace the valve will receive two variants of anti-*S. aureus* phages intravenously between one and three times a day for between two and four days up until the surgical operation. The primary endpoint of the study is to measure the phages' concentration in the infected valve in order to identify the optimal phage administration regimen in this infection. The tolerability and pharmacokinetics of the phages in the blood will also be evaluated. Subject to the approval of the ANSM and the *Comité de Protection des Personnes* (ethics committee), the study could begin in the third quarter of 2023.

Thibaut du Fayet, CEO of Pherecydes Pharma, said: “We are very enthusiastic about the idea of evaluating our anti-*S. aureus* phages in this indication that is a major medical issue, with the aim of reducing the mortality rate, which is currently very high. This new clinical trial is in line with our strategy of accelerating our clinical development plan, reinforced by the planned merger with Erytech Pharma. This clinical study should also enable us to validate a new route of administration (intravenous), which is critical for our clinical development. The results obtained thus far in our preclinical models suggest

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.

² Murdoch D.R., Corey G.R., Hoen B., et al. Clinical presentation, etiology, and outcome of infective endocarditis in the 21st century: the International Collaboration on Endocarditis-Prospective Cohort Study. *Arch Intern Med* 2009; 169: 463-73.

³ Habib G, Lancellotti P, Antunes MJ, et al. 2015 ESC guidelines for the management of infective endocarditis: The task force for the management of infective endocarditis of the European society of cardiology (ESC): Endorsed by: European association for cardio-thoracic surgery (EACTS), the European association of nuclear medicine (EANM). *Eur Heart J* 2015 Nov. 21;36(44):3075-3128. doi: 10.1093/eurheartj/ehv319. Epub 2015 Aug. 29



that phage therapy could have enormous advantages, notably in terms of reducing morbi-mortality; this confirms the merits of our clinical strategy based on the targeting of diseases with substantial unmet medical needs. Endocarditis will be the third clinical indication targeted by Pherecydes Pharma's anti-S. aureus phages, after bone and joint infections on prostheses and diabetic foot ulcers".

About Pherecydes Pharma

Founded in 2006, Pherecydes Pharma is a biotechnology company that develops treatments against resistant bacterial infections, responsible for many serious infections. The Company has developed an innovative approach, precision phage therapy, based on the use of phages, natural bacteria-killing viruses. Pherecydes Pharma is developing a portfolio of phages targeting 3 of the most resistant and dangerous bacteria, which alone account for more than two thirds of hospital-acquired resistant infections: Staphylococcus aureus, Escherichia coli and Pseudomonas aeruginosa. Headquartered in Nantes, Pherecydes Pharma has a team of around twenty experts from the pharmaceutical industry, biotechnology sector and academic research. Pherecydes Pharma announced on February 15, 2023 its plan to merge with Erytech, which will be subject to the approval of the respective shareholders of both companies.

For more information, www.pherecydes-pharma.com

Contacts

Pherecydes Pharma

Thibaut du Fayet

CEO

investors@pherecydes-pharma.com

NewCap

Dusan Oresansky / Nicolas Fossiez

Investor Relations

pherecydes@newcap.eu

T.: 01 44 71 94 92

NewCap

Arthur Rouillé

Media Relations

pherecydes@newcap.eu

T.: 01 44 71 00 15

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