

## Pherecydes Pharma obtains ANSM approval for its PhagoDAIR program, the world's first study in precision phage therapy

- PhagoDAIR is a phase I/II clinical study with anti-Staphylococcus aureus phages in the treatment of osteoarticular infections of prostheses caused by this bacterium
- Patient enrollment should begin during the spring of 2022, subject to CPP (Patient Protection Committee) approval
- The first results of the study are expected in the summer of 2023

Nantes, December 22, 2021 – 7 am CET - 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 obtained ANSM (French National Agency for the Safety of Medicines) approval to carry out a phase I/II clinical study – PhagoDAIR – in the treatment of osteoarticular infections of prosthetic joints caused by *Staphylococcus aureus*.

The World Health Organization (WHO) considers *Staphylococcus aureus* (*S.-aureus*) to be a high priority pathogenic agent in terms of the research and development of new treatments<sup>1</sup>, given that over 25% of *S. aureus* strains are antibiotic-resistant. In osteoarticular infections of prosthetic joints, the indication targeted by the PhagoDAIR study, 30% to 50% of cases are due to resistant *S.-aureus*<sup>2</sup>.

PhagoDAIR is the world's first study of phage therapy to be carried out in this indication. It will be undertaken in France and Spain on 60 patients with a knee or hip joint infection due to *S.-aureus*, divided into one group who will be treated with phage therapy and another group who will receive a placebo, in addition to the standard of care. The patients treated with phage therapy will receive anti-*Staphylococcus aureus* phages that are active on their strain, selected thanks to Pherecydes Pharma's phagogram. The standard of care will comprise the surgical procedure called DAIR (Debridement, Antibiotics, Implant Retention) combined with a suppressive antibiotic therapy.

The study's objectives will be to assess the efficacy and tolerance of phages combined with DAIR, a surgical procedure during which the phages are applied. This assessment will be undertaken 12 weeks after the DAIR surgical procedure, and patients will continue to be monitored for 2 years.

Pherecydes Pharma is planning to initiate patient enrollment in the spring of 2022, once it receives the approval of the CPP Patient Protection Committee, which will meet in January 2022. The results are expected in the summer of 2023 and monitoring will continue through to the first half of 2025. Depending on the preliminary results of the phase I/II study, Pherecydes Pharma intends to carry out a phase III study in the same indication that could begin at the end of 2023.

Guy-Charles Fanneau de La Horie, Chairman of the Executive Board of Pherecydes Pharma, commented: "The ANSM's approval of the protocol of the PhagoDAIR clinical study is excellent news for our Company, but also for the many patients suffering from osteoarticular infections on their joint prostheses due to Staphylococcus aureus. Indeed, this is the first study in this indication using phage therapy, and we are eager to assess our winning phages, specifically selected for their activity on this particularly hard-to-treat bacterium. This study is one of the pillars of our development strategy

 $<sup>^{1}\, \</sup>underline{https://www.who.int/fr/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed}$ 

<sup>&</sup>lt;sup>2</sup> Wouthuyzen-Bakker et al (2019)

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presented at the time of our IPO, in early 2021, and its upcoming launch brings us even closer to our goal of becoming a world leader in phage therapy".

## **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*. The concept of precision phage therapy has been successfully applied in several dozen patients in the context of compassionate use, under the supervision of the French National Agency for the Safety of Medicines (ANSM). Headquartered in Nantes, Pherecydes Pharma has a team of around twenty experts from the pharmaceutical industry, biotechnology sector and academic research.

For more information, www.pherecydes-pharma.com

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