A world first: Pherecydes Pharma launches multicenter clinical study of phage therapy in serious burn victims

For the first time, an industry-standard clinical trial is evaluating the tolerance and effectiveness of phages in fighting sensitive antibiotic-resistant infections

Romainville, France, September 9, 2015 – Pherecydes Pharma, a biotechnology company specialized in the research and development of therapeutic lytic bacteriophages, announces today the launch of the Phagoburn clinical trial. This randomized and monitored phase I/II single-blind trial aims to evaluate the tolerance and effectiveness of two anti-infection bacteriophage treatments in serious burn patients. The effect of the bacteriophages is compared to a reference treatment: silver sulfadiazine.

Phage therapy is an innovative therapeutic method for treating bacterial infections, in particular hospital-acquired infections and/or antibiotic-resistant infections. This is the first international clinical study on phages in the world that meets international standards in clinical evaluation. It will involve 220 patients spread across two arms: 110 patients for each of the two bacteriophages cocktails developed by Pherecydes Pharma. One of the products targets bacterial infections caused by *Escherichia coli*, the other targets infections caused by *Pseudomonas aeruginosa*. Infections involving these germs are often very severe. These species frequently and rapidly attain high levels of resistance to antibiotics. This can be fatal if therapy fails. The trial began in July 2015.

Phagoburn is coordinated by the Percy Military Hospital (France), a Service de Santé des Armées (SSA) Hospital within the French Ministry of Defence. It is being conducted in 11 major burns units in France, Switzerland and Belgium. Two other military hospitals are involved in the project – the Reine Astrid Hospital in Brussels (Belgium) and the Sainte-Anne Military Hospital in Toulon (France). Eight civilian hospitals are also taking part: the Liège teaching hospital (CHU) and the Grand-Hôpital of Charleroi-Loverval (Belgium), the Vaud CHU (Switzerland), the St. Joseph/St. Luc Hospital in Lyon, the Nantes and Bordeaux CHUs, the Metz-Thionville regional hospital and the Conception hospital in Marseille (France).

Clean Cells, a French pharmaceutical company, carried out the bioproduction of the phages in line with current pharmaceutical good manufacturing practices (GMP). CRO Statitec (France), which is responsible for managing the trial data and statistical aspects, is also participating in the project.

"Infections are the most common cause of mortality in burn patients," said Dr. Patrick Jault, head of the anesthesia unit at the Percy Hospital and principal investigator for the trial. "Pherecydes' approach, involving the use of phages, is an interesting one for us because it has the potential to open up a new avenue for therapy to counter antibiotic resistance through the use of a very rigorous procedure. This study is the result of a close collaboration between all of the stakeholders (SMEs, doctors, pharmacists, regulators, politicians etc.), with the goal of providing a common response to a public health issue."

"The launch of this clinical trial is a big step for Pherecydes Pharma. Phagoburn has received all the necessary authorizations in France, Switzerland and Belgium; a testament to the quality of our phage therapy method and the development work put into the products tested," said Jérôme Gabard, CEO of Pherecydes Pharma. "Phage therapy is a promising solution to the problem of bacterial resistance. We see our therapy as both an alternative and a supplement to antibiotic treatment."

The WHO[1] estimates that, in Europe and the United States, hospital-acquired infections (HAIs) affect 4 million and 1.7 million patients respectively. They are responsible for 147,000 and 99,000 direct and indirect fatalities each year. The annual costs incurred are estimated at €7 bn ($7.82bn) in Europe and $6.5bn (€5.82bn) in the United States. The rapid growth of antibiotic resistance means that this is a major public health issue.

Phagoburn is part of a European FP7 project. The study, launched in June 2013 for a period of three years, has received €3.85 million ($4.3 million) in European Union funding. www.phagoburn.eu.

About phage therapy

Phage therapy involves using lytic bacteriophage viruses (more commonly known as phages) to treat bacterial infections. This type of treatment was widely used across the world on a more informal basis before the discovery of antibiotics. Today it can be found in the pharmacopoeia of Georgia, Poland and Russia.

Since the early 2000's, given the emergence of HAIs involving multi-resistant bacteria and in the absence of new and effective antibiotics, a modern form of phage therapy has been emerging in numerous countries. In Europe, this revival can be traced back to 1994 when the use of phages to treat an infection caused by Pseudomonas aeruginosa proved effective during skin grafts. Since then, a number of other studies on animals have led to further interest in this kind of treatment.

About Pherecydes Pharma

Pherecydes Pharma SA specializes in research and development of therapeutic and diagnostic products based on lytic bacteriophage (or phages). The company offers innovative and adaptive solutions to multi-resistant bacteria through its research into natural phage cocktails.

Thanks to its unique expertise in rapidly identifying and isolating natural lytic phages, Pherecydes Pharma has managed to develop a large bank of bacteriophages cocktails to fight antibiotic-resistant infections, which have risen steadily since the 1980s. The company owns the world's largest collection of phages against Escherichia coli. It is also working on Pseudomonas and staphylococci. These three bacterial species alone are responsible for more than 50% of infections in industrialized countries. Half a dozen patents have been filed or are in the process of being registered in order to protect the technology and products developed by Pherecydes Pharma. In addition to the two products being tested in the Phagoburn clinical trial, the company is developing two other products: one for the treatment of respiratory tract infections the other for treating bone and joint infections and diabetic ulcers. The latter targets staphylococci infections.

Located in the Biocitech science park near Paris, Pherecydes Pharma has ten employees and plans to hire a further half-dozen in 2016. Having raised €2.3 million ($2.57 million) since it was founded in 2007, the company raised an additional €2.6 million ($2.9 million) from private investors in March 2015. It also benefits from public funding from the Ministry of Defense (PneumoPhage project), the Single Inter-Ministry Fund (Phosa project) and the European FP7 grant for the Phagoburn project.

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[1] http://apps.who.int/iris/bitstream/10665/80135/1/9789241501507_eng.pdf?ua=1