













PRESS RELEASE

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PHAGOBURN, first European clinical study on phage therapy to treat *Escherichia coli* and *Pseudomonas aeruginosa* skin infections in burn patients

PHAGOBURN is a European collaborative project funded by the 7th Framework Programme for Research and Development (Health Programme). It has been launched on June 1st, 2013 and will last 27 months. Under the coordination of the French Ministry of Defence (Army Health Service – Percy Military Hospital) collaborating with Pherecydes Pharma (French SME), PHAGOBURN gathers six other international burn treatment centres – including the Royal Military Academy/Queen Astrid Military Hospital (Belgium) and the Lausanne University Hospital (Switzerland) – as well as a second French SME, Clean Cells.

The PHAGOBURN study aims at evaluating phage therapy (therapeutic use of bacteriophages) to treat skin infections caused by *Escherichia coli* and *Pseudomonas aeruginosa* bacteria in burn patients.

Phage therapy interest is based on natural predators destroying bacteria: bacteriophages. These environmental viruses are found wherever bacteria exist, and it is recognised that they represent Earth most important biomass.

Due to their antibacterial action, the use of bacteriophages for therapeutic purposes started right after their discovery, at the beginning of the 20th century. Nevertheless, the advent of antibiotics in the late 1930s (perceived as "miracle" drugs) and the Second World War (resulting in their mass production) led to phage therapy decline. Yet its use remained in countries located beyond the Iron Curtain, which did not have access to Western world antibiotics at that time.

However, the current and growing emergence of antibiotic-resistant bacterial strains in hospital settings creates complex therapeutic problems. It sometimes leads to dramatic deadlocks for patients, as the last antibiotics active against these bacteria are over 20 years old. In addition, antibiotic therapy research – mostly focused towards community medicine – offers little hope for an efficient antibiotic against hospital bacteria, including in the long-term. In the face of these threats and weaknesses, there is a strong risk for nosocomial infections to become orphan diseases in the near future. Thus other and complementary means to antibiotic therapy for combating these resistant infections are needed. Phages use seems highly promising, which explains a renewed interest from health professionals, public authorities and patients' associations. At this stage, Georgia, Poland and Russia successfully implement phage therapy on a large scale. Unfortunately, such local use cannot be transferred directly to Europe as a whole. Based on obvious public health objectives it is therefore essential to launch research programmes adapted to our standards, so as to validate phage therapy according to Western criteria.

The PHAGOBURN project is consistent with this strategy. It specifically addresses burn patients, for which infections are the leading cause of death. In particular, focus is on infections caused by *E. coli* and *P. aeruginosa* bacteria, which are often the source of serious, hard-to-treat pathologies, and which incidence is increasing. Phage therapy efficacy and safety will be evaluated through a phase I/II clinical study in accordance with Good Clinical and Manufacturing Practices (GCP and GMP). This clinical trial, to be carried out in France, Belgium and Switzerland within hospital units dedicated to burn patients' care, is the first of its kind at world scale.

PHAGOBURN has a total budget close to 5 million euros, with a European funding of over 3.8 million euros.





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