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Drug candidate from hen's eggs can replace antibiotics

The European Commission has granted Swedish researchers over €5 million to conduct a clinical phase III study on patients with cystic fibrosis.

Antibodies from hen's eggs (IgY) may shortly come to revolutionize the treatment of patients suffering from the incurable disease cystic fibrosis. Most patients with cystic fibrosis are affected by severe and ultimately chronic infections with *Pseudomonas aeruginosa* bacteria. To date, the only treatment has been repeated courses of antibiotics, with a high risk of side effects and bacterial resistance. The IgY-method, using antibodies from hen's eggs, prevents infections and is also interesting as an alternative treatment to antibiotics in the struggle against other bacteria where the trend is an increase in the resistance. Antibiotic resistance is today the single most alarming threat against common health in Europe.

Following a multiyear Swedish clinical trial with good results at multiple centers including the CF-centre in the Uppsala University Hospital, the Uppsala-based company Immunsystem IMS with partners has been granted over €5 million from the European Commission to conduct a so-called phase III study. This is the last major step before a drug candidate can be filed for marketing authorization.

Cystic fibrosis (CF) is a hereditary disorder with repeated respiratory infections and malnutrition as main clinical manifestations. Nearly all CF patients are affected by infections in the lungs by the bacteria *Pseudomonas aeruginosa*. Chronic infections with this bacteria lead to respiratory failure and is the major cause of premature death. Treatment with antibiotics has raised the life expectancy of CF patients, but the treatment often gives side effects in the form of allergies and intestinal problems. Continuous use of antibiotics also increases the risk that the bacteria become resistant. Antibiotic resistance is the greatest threat against common health in Europe today, and therefore the EU's expert panel looks positively on the study.

The drug candidate, Anti-*Pseudomonas* IgY, is a solution with antibodies specifically targeting *Pseudomonas aeruginosa*. The hen is vaccinated with the bacteria and will thereby start producing antibodies that are transferred to the egg in a high concentration. When the patient gargles with the solution, the antibodies will attack the flagella of the bacteria preventing them from attaching to the cell walls in the patient's mouth and throat. This in turn prevents the bacteria from further infecting the lungs. Since we are constantly exposed to these ubiquitous bacteria, CF patients need continuous protection. Anti-*Pseudomonas* IgY is a water based solution, free from any other additives. As a natural and safe solution it is especially suited for long-term, prophylactic treatment. Anti-*Pseudomonas* IgY can be given daily without any side effects since eggs have been a part of our natural diet since the beginning of time. A group of patients in Sweden has been given the treatment for close to 15 years, and a clear delay in the recurrence of *Pseudomonas aeruginosa* infections has been observed. This treatment has also indicated a diminished use of antibiotics, a decrease in hospitalization days, and a decrease in required health care.

Immunsystem IMS, an Uppsala-based company who holds the patent, has in collaboration with Uppsala University been granted financing for a clinical phase III study of Anti-Pseudomonas IgY for treatment of CF patients. CF centers from several European countries are participating in the study which is coordinated by Uppsala University. The European Commission found the concept of the study interesting and that it held a high novelty value. A reduction in the use of antibiotics is seen as particularly important. The Commission also claims that the safety risks of the study are very limited, if any. Anti-Pseudomonas IgY has previously been granted an Orphan Drug Designation by the European Medicines Agency (EMA) for the treatment of CF. For Immunsystem, the Orphan Drug Designation gives the company ten years exclusivity on the market after the drug is granted marketing authorization.

The IgY method, using antibodies from hen's eggs, is also a highly interesting alternative to antibiotics in the fight against other bacteria where the trend is towards increasing resistance. Currently, another project is ongoing where IgY antibodies are used against intestinal ESBL bacteria. ESBL bacteria, resistant against antibiotics, have caused a number of difficult outbreaks at Swedish hospitals, for example in newborns.

Contacts:

General information on the IgY method, application areas, developing opportunities, etc.

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Information on IgY as a treatment method for Cystic fibrosis patients and phase III study

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