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Immunsystem is Granted Orphan Drug Status for Substance for Treatment of Cystic Fibrosis

Swedish biotech company Immunsystem I.M.S. AB has been granted orphan drug status by the European Medicines Agency EMEA for their drug candidate Anti-Pseudomonas IgY for the treatment of cystic fibrosis.

Cystic fibrosis is a hereditary disease with clinical manifestations mainly in the airways and in the gastro-intestinal canal. Lung infections with the bacteria *Pseudomonas aeruginosa* are very common and troublesome. Chronic infections with this bacteria can lead to respiratory failure, and this is the most frequent cause of premature death in these patients.

Treatment of lung infections with antibiotics has increased the average life expectancy for patients with cystic fibrosis to around 40 years of age, but the treatment is often associated with side-effects such as intestinal problems and allergies. The continuous use of antibiotics also increases the risk of the bacteria developing resistance, which presents a grave problem for the patients as well as healthcare as a whole.

Anti-Pseudomonas IgY is a solution containing antibodies specifically targeted against *Pseudomonas aeruginosa*. The solution, which is produced from hen eggs, protects against the bacteria in the mouth and throat which prevents the bacteria from further infecting the lower airways. A group of patients in Sweden has been treated for more than ten years, and it is clear that the time between pseudomonas infections is significantly increased. Further, the usage of antibiotics and the number of days spent hospitalized has been reduced.

Resistance to antibiotics presents the greatest health threat in Europe today. Every year, three million Europeans are infected by resistant bacteria and about 50,000 of them die. The reason for this very alarming development is the excessive use of antibiotics and limiting their use is very important.

"We are exposed to these bacteria every day, and for cystic fibrosis patients a continuous protection is needed. Anti-Pseudomonas IgY is ideally suited for long-term prophylactic treatment since it is a natural and safe solution that can be given daily without any side-effects" says Hans Kollberg, Head of clinical research at Immunsystem.

The classification of Anti-Pseudomonas IgY as an orphan drug means that the costs for development and the time to market can be reduced considerably. It also means that the company is granted ten years of market exclusivity after the drug has been approved for marketing. The legislative framework of orphan medicines was introduced by the European parliament in 2000 and is intended to encourage the development of drugs that target rare diseases for which there is no efficient treatment.

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Immunsystem I.M.S. AB was founded in 1983 by researchers from Uppsala University and the Swedish University of Agriculture. The company specializes in the production and use of antibodies within therapeutics as well as diagnostics. The company has several patents in therapeutic areas where clinical trials of long-term prophylactic treatment have been carried out. Please visit our homepage www.immunsystem.com for more information.