

PRESS RELEASE

Cystic fibrosis – Orphan drug designation for innovative treatment against lung infections by Axentis Pharma AG

Zurich, 30 April 2009. An innovative treatment for infections of the respiratory tract in cystic fibrosis patients has received orphan drug designation in the US. Axentis Pharma AG of Zurich, Switzerland announced today that this sought-after designation has been granted to its product candidate Fluidosomes™-tobramycin, a therapeutic that will soon be tested in Phase II clinical trials. The company has now been granted orphan drug designation for this candidate in both Europe and the US.

Axentis Pharma (Switzerland) announced today that the Office of Orphan Products Development of the US Food and Drug Administration (FDA) has granted the orphan drug designation to its lead product candidate Fluidosomes™-tobramycin. This drug is a liposomal formulation of tobramycin, an innovative treatment for infections of the respiratory tract in patients with cystic fibrosis that is delivered directly to the site of infection via standard nebulizers. Pre-clinical and Phase I clinical studies support improved safety and efficacy profiles for Fluidosomes™-tobramycin as compared to currently marketed treatments for infections of the respiratory tract in patients with cystic fibrosis.

The orphan drug designation is granted with respect to treatment of pulmonary infections caused by *Pseudomonas aeruginosa*, a bacterium that is one of the most common causes of infections of the respiratory tract in patients with cystic fibrosis. Axentis Pharma's product candidate received orphan drug designation for the US only two months after the application and less than one year after orphan designation in Europe was transferred to the company.

Dr. Helmut Brunar, company CEO and President, comments: "The orphan drug designation for the US is very good news for affected patients as well as for Axentis Pharma's shareholders. Together with the Orphan Drug Designation that was already achieved last year in Europe, the US Designation puts Axentis Pharma in a favourable position to register Fluidosomes™-tobramycin in two major world markets with substantial support of the relevant authorities and at a cost advantage for the company. As a result, we will be able to deliver the product at competitive prices to patients once it has passed the final clinical test phase. In addition to this, the orphan drug designation grants Axentis several years of exclusive marketing rights once the product has been launched. That is a significant strengthening of Axentis' Pharma's market position as well as the company's value."

Fluidosomes™-tobramycin combines the company's proprietary Fluidosomes™ technology with the well-established generic drug tobramycin. Utilising synthetic liposomes containing tobramycin, a standard nebulizer delivers the drug directly to the endobronchial sites of infection in cystic fibrosis patients. This may result in prolonged high local drug concentration in the lung, which in turn may lead to higher efficacy and may allow lower doses.

Currently, the company is initiating Phase II clinical trials that will assess the safety and tolerability of a new therapeutic formulation as well as the effects of two different doses of the new drug. Results of the clinical trial are expected early 2010.

About Axentis Pharma AG (www.axentispharma.com)

Axentis Pharma is a respiratory specialty pharmaceutical company which core competence is the application of a fully patented, encapsulating drug delivery system to already established and well-characterized therapeutic agents. Currently, the company is using this technology, named Fluidosome™ technology, for the development of its lead product, a clinical stage treatment against cystic fibrosis (CF).

About Fluidosome™ technology

Axentis Pharma's Fluidosome™ technology uses biocompatible lipids endogenous to the lung that are formulated into small liposomes. This nanocapsule platform offers wide-ranging potential for unmet medical needs, including other respiratory diseases. In the case of Fluidosome™-tobramycin, the interaction between tobramycin and the microbial cell is triggered when the liposomes attach to the outer cell membrane. Tobramycin then leaches into the inner cell compartment, which leads to rapid cell death.

About cystic fibrosis

Cystic fibrosis is the most common life-threatening hereditary disease amongst Caucasian populations. The disease is caused by a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene found on chromosome 7. This mutation causes increased secretion deposits on mucous membranes. Lung complications represent the most serious manifestation of the disease – and the reason for the high mortality rate amongst patients. Such complications often involve infection of the bronchi by the bacteria *Pseudomonas aeruginosa*. Chronic inflammations then cause lung functions to become blocked. As well as the breakdown of lung tissue, this also leads to bronchiectasis and lung failure.

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