

## PRESS RELEASE

### **Cystic Fibrosis: License Agreement Boosts Development of Therapy Against Lung Infections**

**Zurich, 19. December 2007: An exclusive license for the development and commercialisation of a drug delivery system for lung infections in Cystic Fibrosis patients was signed today. As part of the agreement, aRigen Pharmaceuticals Inc., Japan transferred relevant rights to Axentis Pharma AG of Switzerland. The EMEA has already granted orphan drug status to the licensed technology and a phase II clinical trial will be initiated by Axentis Pharma AG in early 2008.**

Axentis Pharma AG (Switzerland) and aRigen Pharmaceuticals, Inc. (Japan) announced today the signature of a license agreement for the development of therapy against lung infections in Cystic Fibrosis patients. Under the terms of the agreement Axentis Pharma AG purchased from aRigen Pharmaceuticals, Inc. an exclusive license for the development and commercialisation of ARB-CF0223 worldwide except Japan and Korea. ARB-CF0223 is a fully patented, innovative encapsulating drug delivery system for the treatment of pulmonary infections in patients with Cystic Fibrosis. The system has an improved safety profile, higher efficacy and lower doses, and also reduces the frequency and severity of exacerbations compared to current treatments for pulmonary infections in patients with Cystic Fibrosis. As part of the agreement aRigen Pharmaceuticals, Inc. received shares of Axentis Pharma plus an undisclosed sum in cash.

Jörg Zielasek, President of Axentis Pharma AG, commented that: "The purchase of the license from aRigen Pharmaceuticals grants Axentis the right to further develop and commercialise an extremely promising treatment for chronic lung inflammation, the most severe consequence of Cystic Fibrosis. The agreement means that Axentis can now initiate an immediate phase II clinical trial in Germany. The design of the study has already been approved by the EMEA, which has also granted orphan drug status to ARB-CF0223. This is a very promising prospect for both Cystic Fibrosis patients and investors in Axentis."

Mr. Toru Gensuke Tokoro, President and CEO of aRigen Pharmaceuticals, Inc. adds: "ARB-CF0223 is based on a well-characterised drug, Tobramycin. Utilising synthetic liposomes that contain Tobramycin, a proprietary nebulizer delivers the drug directly to the endobronchial sites of infection in Cystic Fibrosis patients. This results in prolonged, high local drug concentration, which in turn achieves higher efficacy and lower doses. We are pleased that a competent partner such as Axentis Pharma will further develop this promising product."

The drug has already been tested successfully in a phase I single-dose inhalation study. No significant adverse events were observed when the liposomal formulation of Tobramycin was compared with the currently marketed formulation in 24 healthy volunteers who were treated in a crossover fashion.

**About Axentis Pharma AG ([www.axentispharma.com](http://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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