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CONTACT: Jennifer Corrigan,  
732-382-8898  
[jenn.corrigan@comcast.net](mailto:jenn.corrigan@comcast.net)

**TRANSAVE ANNOUNCES POSITIVE PHASE II RESULTS FOR ONCE-DAILY  
ARIKACE™ IN THE TREATMENT OF CYSTIC FIBROSIS PATIENTS WHO HAVE  
PSEUDOMONAS LUNG INFECTIONS**

*Data Presented at the European Cystic Fibrosis Society Conference*

MONMOUTH JUNCTION, NJ, June 13, 2008 – Transave, Inc., today reported positive results from a Phase II clinical trial on its lead investigational drug, *Arikace™* (liposomal amikacin for inhalation). The compound is being developed for the treatment of cystic fibrosis (CF) patients who have lung infections due to the bacterium *Pseudomonas aeruginosa*. The Phase II data indicated that *Arikace*, delivered once daily for 28 consecutive days, produced a significant improvement in lung function, was well-tolerated, and had a side-effect profile comparable to placebo. The Phase II trial was a randomized, double-blind, placebo-controlled study of 64 patients from 15 centers in Europe. Results were presented today at the 31<sup>st</sup> European Cystic Fibrosis Society (ECFS) Conference in Prague, Czech Republic, by Lieven Dupont, MD, Associate Professor of Respiratory Medicine at the Katholieke Universiteit, Leuven, Belgium, and co-lead investigator of the study.

*Arikace* is a novel molecular entity comprised of the antibiotic amikacin, which is enclosed in nanocapsules of lipids called liposomes. *Arikace* was administered once daily for 28 days at 280 mg and 560 mg dosages, using a novel inhalation device, the eFlow<sup>®</sup> Electronic Nebulizer (PARI Pharma GmbH).

The intent-to-treat analysis for efficacy demonstrated that *Arikace*, when administered once daily either at 280 mg or 560 mg for 28 days, resulted in clinically significant improvement in lung function at the end of treatment. This improvement was dose-dependent and was sustained at 28 days after completion of dosing, which was day 56 of the study. Pulmonary function (FEV1) increased significantly among patients receiving the 560 mg dose of *Arikace*, with a sustained treatment effect of 224 ml (p=0.004) and 17.6% (p=0.009) increase compared to placebo, at day 56.

*Arikace* was well tolerated, with no differences observed in the overall rates of adverse events or drug-related adverse events between groups. Fewer serious adverse events, pulmonary exacerbations, and hospitalizations were observed in patients receiving *Arikace* compared to placebo. Additionally, the time to receiving anti-pseudomonal rescue treatment was prolonged for the patients in the *Arikace* arm, as compared to those in the placebo arm, which further confirms the clinical benefit of *Arikace*.

“The magnitude and sustained improvement in lung function provided by *Arikace* administered once-daily may contribute to advances in treatment options for cystic fibrosis patients who have *Pseudomonas* lung infections,” said Renu Gupta, MD, Transave’s Executive Vice President for Development and Chief Medical Officer. Dr. Gupta indicated that the company will seek to confirm the positive Phase II results in a Phase III trial. “This formulation of liposomal amikacin was specifically designed for sustained release and penetration of the mucus and biofilm in the lungs, and we believe

it will provide benefit to patients with cystic fibrosis. These results support the potential value of delivering amikacin through Transave's next-generation liposomal technology."

The biofilm is a gel-like matrix in the lungs formed by colonies of the common and often chronic bacterium *Pseudomonas aeruginosa*, which creates a protective barrier for the bacteria. This barrier often prevents patients with CF from clearing infections, even under aggressive antibiotic treatment. *Arikace* was designed with small (0.3  $\mu\text{m}$ ), neutrally-charged liposomes that enable penetration of the biofilm, which may be an important advantage for improving treatment of lung infections due to *Pseudomonas*. At both the 280 mg and 560 mg doses, patients achieved a reduction in the density of *Pseudomonas* that was greater than the reduction achieved by placebo. Patients receiving the 560 mg dose achieved a 2.2 log reduction in bacterial density.

"This potential new therapy for those with chronic *Pseudomonas* infections is very promising. We are excited to see improvement in pulmonary outcome measures in patients taking *Arikace*," said Robert J. Beall, PhD, President and CEO of the Cystic Fibrosis Foundation. "We are particularly pleased that an award from our Therapeutics Development Program has enabled this promising result for a novel drug delivery system."

Cystic Fibrosis Foundation Therapeutics, the nonprofit affiliate of the Cystic Fibrosis Foundation, provided a \$1.7 million award to support the development of *Arikace*. The Foundation is the leading organization devoted to curing and controlling cystic fibrosis.

"A once-daily drug that is safe and well tolerated may offer significant advantages to patients by reducing patient treatment burden and helping to improve adherence to treatment," said Dr. Dupont. "Many cystic fibrosis patients are living longer in a state of chronic infection. The ability to deliver a drug once a day that may penetrate the CF biofilm and achieve a sustained improvement in lung function would be an important advance in this field.

Based on these results, the Data Safety Monitoring Board has recommended an open-label extension of the study, in which patients would be treated with a 560 mg dose of *Arikace* for three additional 28-day on-treatment and 28-day off-treatment cycles.

The data presented today at the 31<sup>st</sup> European Cystic Fibrosis Society Conference are currently available on the company's website:

(<http://www.transaveinc.com/NewsEvents.aspx?category=Articles&archive=false>).

#### **About *Arikace*<sup>TM</sup> (liposomal amikacin for inhalation)**

*Arikace* is a form of the antibiotic amikacin, which is enclosed in nanocapsules of lipid called liposomes. This proprietary next-generation liposomal delivery technology prolongs the release of amikacin in the lungs while minimizing systemic exposure. The treatment uses biocompatible lipids endogenous to the lung that are formulated into small (0.3  $\mu\text{m}$ ), neutrally-charged liposomes that enable penetration of the biofilm and are highly efficient, with a very low lipid-to-drug ratio (0.65). *Arikace* can be delivered through nebulization, which enables the small aerosol droplet size (~3.0  $\mu\text{m}$ ) to facilitate more effective distribution in the lungs. In addition to clinical studies in CF patients with *Pseudomonas* lung infections, clinical development has been initiated in non-CF bronchiectasis patients with *Pseudomonas* lung infections. *Arikace* has been granted

orphan drug status in the United States by the FDA, and has received an orphan drug designation in Europe by the European Medicines Agency for the treatment of *Pseudomonas* infections in patients with CF.

#### **About PARI Pharma and the eFlow® Electronic Nebulizer**

*Arikace* is delivered by a novel inhalation device, the eFlow® Electronic Nebulizer, developed by PARI Pharma GmbH. eFlow is a quiet, portable nebulizer that enables efficient aerosolization of liquid medications, including liposomal formulations such as *Arikace*, via a vibrating perforated membrane. Based on its 100-year history of working with aerosols, PARI Pharma is dedicated to advancing inhalation therapies by developing innovative delivery platforms and new pharmaceutical formulations that work together to improve patient care.

#### **About the Cystic Fibrosis Foundation**

The Cystic Fibrosis Foundation is the leading organization devoted to curing and controlling cystic fibrosis. Headquartered in Bethesda, MD, the Foundation funds CF research, has 80 chapter and branch offices throughout the country, and supports and accredits a nationwide network of 115 CF Care Centers, which provide vital treatments and other CF resources to CF patients and their families. For more information, visit [www.cff.org](http://www.cff.org).

#### **About Transave, Inc.**

Transave, Inc., is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases. The company's major focus is on developing antibiotic therapy delivered via proprietary next-generation liposomal technology in areas of high unmet need in respiratory diseases. The Transave team is dedicated to leveraging its advanced liposomal development and commercialization expertise, along with its intellectual property, to bring life-extending and life-enhancing medicines to patients. For more information about Transave's technology and development programs, visit <http://www.transaveinc.com/>.