

## FOR IMMEDIATE RELEASE

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### TRANSAVE COMPLETES ENROLLMENT IN ARIKACE™ PHASE II BRONCHIECTASIS STUDY Presently No Approved Treatments

MONMOUTH JUNCTION, NJ, April 21, 2009 – Transave, Inc., today reported completion of patient enrollment in a Phase II study evaluating the safety and efficacy of **Arikace™** (liposomal amikacin for inhalation) in non-cystic fibrosis (CF) bronchiectasis patients. The results, which are expected to be available by mid-year, will shed new light on how this patient population responds to treatment. Presently, there are no approved treatments for the disease.

“Today’s announcement marks the achievement of yet another important milestone in the development of **Arikace** for chronic lung infections,” said Tim Whitten, Transave’s Chief Executive Officer. “We believe **Arikace** has the potential to be an important new treatment for non-CF patients with bronchiectasis. We look forward to seeing the Phase II results in June and moving to Phase III as soon as possible.”

The double-blind, placebo-controlled study is designed to evaluate **Arikace** in non-CF patients who have bronchiectasis with *Pseudomonas* lung infections. In the trial, 64 adult patients were randomized 2:1 to **Arikace** – either a 280 mg or a 560 mg dose – or placebo for 28 days, followed by a 28-day off-treatment observation period. **Arikace** and placebo are administered once daily using an Investigational eFlow® Nebulizer System (PARI Pharma GmbH), a novel, highly efficient, portable aerosol delivery system. Sixteen clinical sites throughout Europe and India are participating in the study.

Bronchiectasis is characterized by localized, irreversible enlargement of the bronchial tubes. Involved bronchi are dilated, inflamed, and easily collapsible, resulting in airflow obstruction and impaired clearance of secretions. The accumulation of mucus in the bronchi leads to frequent infections, which further reduce lung function in these patients. One of the most frequent pathogens infecting bronchiectasis patients is *Pseudomonas aeruginosa*, which is associated with increased sputum production, more extensive bronchiectasis, more hospitalizations, and reduced quality of life.

The disease is often misdiagnosed and mistaken for asthma or pneumonia. There is currently no drug specifically approved for the treatment of bronchiectasis or the associated lung infections in the U.S.

### **About Arikace (liposomal amikacin for inhalation)**

**Arikace** is a form of the antibiotic amikacin, which is enclosed in nanocapsules of lipid called liposomes. This advanced pulmonary liposome 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 micron), 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 (1 to 5 microns) to facilitate more effective distribution in the lungs. In addition to this clinical study in non-CF bronchiectasis patients with *Pseudomonas* lung infections, clinical development has been initiated in CF patients with *Pseudomonas* lung infections, with positive Phase II results reported in June 2008. **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 an Investigational eFlow Nebulizer System developed by PARI Pharma GmbH. The Investigational eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared to other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible period of time. Combined with its silent mode of operation, small size (it fits in the palm of the hand), light weight, and efficient battery use, products incorporating eFlow Technology reduce the burden of taking daily inhaled treatments. The Investigational eFlow Nebulizer System and eFlow Technology are proprietary to PARI Pharma and can be optimized to specific drug formulations.

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

Transave, Inc., is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of chronic lung diseases. The company's major focus is on developing antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. The Transave team is dedicated to leveraging its 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/>.