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ARIKACE™ DEMONSTRATES SUSTAINED BENEFIT IN MULTIPLE STUDIES AND OVER MULTIPLE CYCLES OF TREATMENT OF *PSEUDOMONAS* LUNG INFECTIONS IN CYSTIC FIBROSIS PATIENTS

Data Presented at the North American Cystic Fibrosis Conference

MONMOUTH JUNCTION, NJ, October 21, 2010 – Transave, Inc., today reported positive clinical trial results on its lead investigational drug, ARIKACE™ (liposomal amikacin for inhalation), an antibiotic that is entering Phase III development for the treatment of chronic lung infections. The results demonstrate significant clinical benefit and complete the company's Phase II program for the treatment of lung infections due to the bacterium, *Pseudomonas aeruginosa* in cystic fibrosis (CF) patients.

The data from the Phase II clinical program in CF patients with *Pseudomonas* lung infections indicate that ARIKACE, delivered at a dose of 560 mg once daily via an eFlow® Nebulizer System from PARI Pharma GmbH for 28 consecutive days, demonstrated superior clinical benefit compared to placebo as measured by significant and sustained improvement in lung function and reduction in *Pseudomonas* density. This benefit was sustained over multiple cycles as observed in an open-label long-term study. In addition, ARIKACE was well-tolerated with overall events reported as consistent with those expected in a population of CF patients receiving inhaled medicines. Results were presented today at the Cystic Fibrosis Foundation's 24th annual North American Cystic Fibrosis Conference (NACFC) in Baltimore, Maryland, by JP Clancy, MD, Professor, Director, and Raymond K. Lyrene Chair in Pulmonology, Department of Pediatrics, University of Alabama at Birmingham and Children's Hospital of Alabama.

"The sustained improvement in lung function with significant reduction in bacterial density with ARIKACE has now been shown consistently in several Phase II studies in patients with cystic fibrosis who have chronic *Pseudomonas* lung infections," said Renu Gupta, MD, Transave's Executive Vice President for Development and Chief Medical Officer. "These consistent results suggest that ARIKACE has the potential to improve upon the standard of care in the treatment of chronic *Pseudomonas* lung infections, and support the launch of Phase III studies to confirm efficacy and safety of ARIKACE."

New data were presented from an open label study that was designed to evaluate ARIKACE over multiple treatment cycles in CF patients with *Pseudomonas* lung infections. Forty-nine patients were enrolled to receive ARIKACE 560 mg daily for 28 days of therapy using a novel inhalation device, the eFlow® Nebulizer System (PARI Pharma GmbH), followed by a 56-day off-treatment observation period for each cycle. FEV1 increased significantly among patients receiving 560 mg of ARIKACE, with a relative improvement from baseline in FEV1 of 8.4% (95% CI +4.7%, +12.0%; $p \leq 0.0001$) at the end of treatment during cycles one to five. More than three quarters of the improvement in lung function was sustained at the end of the 56-day off-treatment period during the five cycles (about 14 months) with a relative improvement from baseline in FEV1 of 6.5% (95% CI +2.5%, +10.4%; $p=0.0018$).

Data were also presented from two placebo controlled studies. In the first placebo controlled study conducted in Europe, ARIKACE was administered once daily for 28 days at 280 mg and 560 mg dosages using the eFlow® Nebulizer System. In the second placebo controlled study conducted in U.S., ARIKACE was administered once daily for 28 days at 70 mg, 140 mg and 560 mg doses also using the eFlow® Nebulizer System.

Studies were prospectively designed to allow for pooled analyses of data. Improvements in lung function were dose-related, with the 560 mg dose resulting in the greatest improvement in lung function which was sustained for 28 days after treatment ended. Specifically, pulmonary function (FEV1) increased significantly among patients receiving 560 mg of ARIKACE, with a relative change from baseline in FEV1 of 8.1% versus 1.1% for placebo (p= 0.033). The treatment effect was sustained for 28 days off treatment at Day 56, with a mean improvement in FEV1 for ARIKACE 560 mg versus placebo of 12.5% (p=0.003).

"Consistent results with once-daily ARIKACE demonstrating clinically important improvements in lung function that are sustained during the off treatment period are very encouraging for the treatment of CF patients with *Pseudomonas* lung infections," said Dr. Clancy. "The CF treating community looks forward to the initiation and completion of Phase III clinical trials and to potentially providing these benefits to our CF patients."

Cystic Fibrosis Foundation Therapeutics, Inc., a nonprofit affiliate of the Cystic Fibrosis Foundation, provided $3.9 million to support the development of ARIKACE. The Foundation is the leading organization devoted to curing and controlling cystic fibrosis.

The data presented today at the 24th annual North American Cystic Fibrosis Conference are currently available on the company's website: (http://www.transaveinc.com/NewsEvents.aspx?category=Articles&archive=false).

About ARIKACE™

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), neutral liposomes that enable penetration of the biofilm.

The company also previously announced positive Phase II results in September 2009 in the treatment of non-CF bronchiectasis patients who have *Pseudomonas* lung infections.

Transave and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), will collaborate on the planning, design and implementation of a clinical trial expected to begin in the first half of next year to evaluate ARIKACE in patients with nontuberculous mycobacteria (NTM) lung disease who have failed to respond to standard, guideline-based treatment regimens. Current treatment requires lengthy multi-drug regimens that are often poorly tolerated and not very effective. No new drugs have been assessed in clinical trials for this disease in many years.

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. ARIKACE has also been granted orphan drug status by the FDA for the treatment of bronchiectasis in patients with *Pseudomonas* or other susceptible pathogens.

About eFlow® Technology and PARI Pharma

ARIKACE is delivered by an eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKACE. The 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. eFlow Technology is not an ultrasonic nebulizer technology, and it is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight, and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to advance aerosol therapies where drug and device can be optimized together. Online at www.paripharma.com.

About The Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation is the world's leader in the search for a cure for cystic fibrosis. The Foundation funds more CF research than any other organization and nearly every CF drug available today was made possible because of Foundation support. Based in Bethesda, Md., the Foundation also supports and accredits a national care center network that has been recognized by the National Institutes of Health as a model of care for a chronic disease. For more information, please visit 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 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 www.transaveinc.com.