

Transave receives Orphan Drug Designation from the FDA for SLIT™ Amikacin for treatment of pulmonary *Pseudomonas aeruginosa* infections in Cystic Fibrosis Patients

MONMOUTH JUNCTION, New Jersey, March 23, 2006 -- Transave, Inc., a biopharmaceutical company focused on the development of inhaled, liposomally formulated drugs for treating life threatening lung diseases, today announced that the Food and Drug Administration (FDA) Office of Orphan Product Development has granted SLIT™ Amikacin orphan drug status for the treatment of bronchopulmonary *Pseudomonas aeruginosa* (Pa) infections in Cystic Fibrosis (CF) patients.

"We are proud to receive the FDA's Orphan Drug designation for SLIT™ Amikacin which provides many benefits for its timely development" said Frank Pilkiewicz, Ph.D., President and Chief Executive Officer of Transave. "Transave is committed to the development of this novel, inhaled antibiotic for the CF patient and the healthcare community. We are grateful for the support provided by the Cystic Fibrosis Foundation and we are happy to have the recognition of the Office of Orphan Products Development."

"Chronic and eventually fatal lung infections remain the number one problem in Cystic Fibrosis," said Robert J. Beall, Ph.D., President and Chief Executive Officer of the Cystic Fibrosis Foundation. "SLIT™ Amikacin approaches these infections via a unique formulation of a traditional antibiotic. We are pleased that the FDA has granted it orphan drug status and look forward to seeing the results of ongoing clinical trials."

CF is a life-threatening, genetic disease affecting approximately 30,000 people in the U.S. Approximately 80% of CF patients are chronically infected with Pa and the infection is associated with a more rapid decline of lung function. More information regarding CF is available through the Cystic Fibrosis Foundation web site www.cff.org. Cystic Fibrosis Foundation Therapeutics, Inc. awarded Transave a \$1.7 million grant for the development of SLIT™ Amikacin.

About SLIT™ Amikacin

Transave's product development candidates are based on its proprietary Sustained release Lipid Inhaled Targeting (SLIT™) technology. SLIT™ Amikacin utilizes lipid constituents endogenous to the lung, i.e. the pulmonary surfactant, resulting in a safe and biocompatible inhalable formulation. In addition, SLIT™ Amikacin is designed to provide for sustained release of the antibiotic, effective penetration of SLIT™ particle through the bacterial biofilm and minimized local and systemic side effects. The product profile of SLIT™ Amikacin should allow for once a day or less frequent dosing with an optimized pharmacokinetic profile which provides both high peak lung concentrations and a prolonged therapeutic effect. Transave has begun a 14-day multi-dose Phase IIa trial to confirm the efficacy and safety of nebulized SLIT™ Amikacin in CF patients with chronic Pa

infections. An earlier single dose Phase I trial in CF patients demonstrated that the drug is well tolerated at all doses with no significant adverse events.

About the Orphan Drug Act

The U.S. Orphan Drug Act is intended to encourage companies to develop therapies for the treatment of diseases that affect fewer than 200,000 individuals in the U.S. Further criteria include the ability of the product to address an unmet medical need where no approved treatment option exists or to provide significant benefit over available treatments. Orphan drug designation, granted by the FDA's Office of Orphan Products Development, provides the company with a number of potential benefits for SLIT™ Amikacin. Approval by the FDA of a drug that has been granted orphan drug designation typically results in seven years of market exclusivity in the U.S., provided that the sponsor company continues to meet certain conditions established by the FDA. In addition, during the period of market exclusivity, the FDA will not approve other applications to market the same drug for the same indication unless the sponsor of the approved orphan drug fails to satisfy the conditions of approval. Other incentives provided by orphan designation include tax credits, protocol assistance and eligibility for research and development support. Protocol assistance includes regulatory assistance and a waiver of certain filing fees, as well as advice on the conduct of clinical trials.

About Transave, Inc. (www.transaveinc.com)

Transave's proprietary SLIT™ technology allows for the sustained release of drug in the lung's microenvironment and targeting to the pulmonary disease site, resulting in enhanced therapeutic benefits and improved dosing regimens. This approach: (1) builds upon the demonstrated efficacy of approved agents in the target diseases; (2) focuses on reducing or eliminating the known systemic toxicities or dosing problems associated with drugs administered systemically and by inhalation via localized administration and controlled release, and; (3) creates a new, improved product profile of a known, well characterized drug. Virtually any compound can be adapted to SLIT™ technology (including peptides, proteins, vaccines), thus allowing Transave to develop multiple product lines and families. By utilizing approved, well characterized drugs, Transave is able to develop therapeutics in a fraction of the time and cost as compared to the development of a new chemical entity.

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