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**For Immediate Release**

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## **DENUFOSOL PROCEEDING TO PHASE 3 TRIALS IN CYSTIC FIBROSIS**

DURHAM, NC – January 30, 2006 – Inspire Pharmaceuticals, Inc. (NASDAQ: ISPH) today announced plans to initiate a Phase 3 program to advance denufosol tetrasodium for the treatment of cystic fibrosis (CF). This follows the successful completion of an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA).

“We are pleased to be moving this high-priority program into Phase 3 development,” said Christy L. Shaffer, Ph.D., President and CEO of Inspire. “At our recent FDA meeting, key aspects of the program were discussed, including preclinical and clinical, and we believe that the FDA’s requirements for approval are consistent with previous regulatory precedents for therapies in CF lung disease. We appreciate the FDA’s guidance on the denufosol program and look forward to working closely with the FDA’s Pulmonary Division as we finalize the details of our Phase 3 program.”

The focus of Inspire’s Phase 3 program will be to develop denufosol for CF as an early intervention therapy for treatment of patients with mild lung disease. Inspire has conducted six studies in support of the denufosol CF program, involving more than 300 patients and volunteers. According to the Cystic Fibrosis Foundation’s 2004 Patient Registry, approximately two-thirds of CF patients have lung disease defined as mild as measured by the standard pulmonary function test, FEV<sub>1</sub> (Forced Expiratory Volume over one second) > 70% predicted. Importantly, in the pediatric population under 18 years of age, approximately 80% of patients have mild or early lung disease.

Based on the End-of-Phase 2 meeting with the FDA, Inspire plans to conduct two pivotal Phase 3 clinical trials in CF patients with FEV<sub>1</sub> as the primary endpoint. The first clinical trial will be a pivotal efficacy trial that will also fulfill the requirement to study denufosol in patients for one year. Initiation of this trial is targeted to begin mid-year 2006. In addition, Inspire is required to conduct a single two-year inhalation carcinogenicity study in one species. The time from initiation of the study to receipt of the final study report is expected to be up to three years. This study is expected to be initiated before the end of 2006, following FDA review of the toxicology protocol.

Robert J. Beall, Ph.D., President and CEO of the Cystic Fibrosis Foundation, commented, “There is tremendous excitement in the CF community for a potential early intervention therapy, such as denufosol. The Cystic Fibrosis Foundation will continue to strongly support Inspire's development program, in particular by increasing awareness of the opportunity for patients to participate in Phase 3 trials of denufosol.”



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Inspire will host a brief conference call and live webcast today at 11:00 a.m. ET to discuss this announcement. To access the conference call, U.S. participants may call (877) 780-2276 and international participants may call (973) 582-2757. The conference ID number is 6978423. A live webcast and replay of the call will be available on Inspire's website at [www.inspirepharm.com](http://www.inspirepharm.com). A telephone replay of the conference call will be available until February 13, 2006. To access this replay, U.S. participants may call (877) 519-4471 and international participants may call (973) 341-3080. The conference ID number is 6978423.

### **About Cystic Fibrosis and Denufosol Tetrasodium**

Cystic fibrosis is a fatal disease involving a genetic mutation that disrupts the cystic fibrosis transmembrane regulator (CFTR) protein. This protein acts as an ion-specific channel that moves salt and water to the surface of the airways. A defect in this ion channel in CF patients leads to poorly hydrated, thick, mucous secretions in the airways and severely impaired mucociliary clearance. There are approximately 75,000 CF patients in the eight major international prescription pharmaceutical markets, based on Inspire internal estimates. According to the Cystic Fibrosis Foundation's 2004 Patient Registry, the median age at CF diagnosis is six months and the median life expectancy for CF patients is 35 years. According to CF experts, the introduction of routine diagnostic testing for CF following birth is anticipated within the next five years and will result in the identification and potential treatment of patients at a very young age.

Denufosol tetrasodium is a selective P2Y<sub>2</sub> agonist designed to enhance the lung's innate mucosal hydration and mucociliary clearance mechanisms by activating an alternative ion channel that acts in the same way as the defective ion channel in moving salt and water to the surface of the airways. Based on pre-clinical and clinical work, denufosol has several pharmacological actions contributing to its mechanism of action: hydration of the airways by stimulating chloride and liquid secretions on the epithelial cell surface; inhibition of epithelial sodium absorption; enhancement of ciliary beat frequency; and stimulation of mucin secretion. This unique mechanism of action represents a differentiated approach relative to other approved CF products and may be important in intervening in the early clinical course of CF lung disease. Denufosol for the treatment of cystic fibrosis has been granted Fast Track designation and orphan drug status in the U.S. by the FDA and orphan drug designation in Europe by the European Medicines Agency (EMA).

### **About Inspire**

Inspire is a biopharmaceutical company dedicated to discovering, developing and commercializing prescription pharmaceutical products in disease areas with significant commercial potential and unmet medical needs. Inspire has significant technical and scientific expertise in the therapy areas of ophthalmology and respiratory and is a leader in the field of P2 receptors which are important drug targets in various therapeutic areas, including ophthalmology, respiratory disease and cardiovascular disease. Inspire's U.S. specialty sales force promotes *Elestat*<sup>®</sup> (epinastine HCl ophthalmic solution) 0.05% and *Restasis*<sup>®</sup> (cyclosporine ophthalmic emulsion) 0.05%, ophthalmology products developed by Inspire's partner, Allergan, Inc. *Elestat* and *Restasis* are trademarks owned by Allergan, Inc. For more information on Inspire, visit [www.inspirepharm.com](http://www.inspirepharm.com).



**About Cystic Fibrosis Foundation**

The mission of the Cystic Fibrosis Foundation, a donor-supported, nonprofit organization, is to assure the development of the means to cure and control cystic fibrosis and to improve the quality of life for those with the disease. The Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT) is the nonprofit drug discovery and development affiliate of the CF Foundation. The CF Foundation provides total support to CFFT. For more information about cystic fibrosis, the CF Foundation or CFFT, visit [www.cff.org](http://www.cff.org), or call (800) FIGHT –CF.

**Forward-Looking Statements**

The forward-looking statements in this news release relating to management's expectations and beliefs are based on preliminary information and management assumptions. Such forward-looking statements are subject to a wide range of risks and uncertainties that could cause results to differ in material respects, including those relating to product development, revenue, expense and earnings expectations, the seasonality of *Elestat*, intellectual property rights, adverse litigation developments, adverse developments in the U.S. Securities and Exchange Commission (SEC) investigation, competitive products, results and timing of clinical trials, success of marketing efforts, the need for additional research and testing, delays in manufacturing, funding, and the timing and content of decisions made by regulatory authorities, including the U.S. Food and Drug Administration. Inspire cannot guarantee the outcome or timing of a Phase 3 program for denufosol for CF. A significant amount of work will be required to advance denufosol through clinical testing, including satisfactory completion of additional clinical trials and toxicology and carcinogenicity studies. There can be no assurance that Inspire, either alone or with the support of any other third party, will be able to recruit sufficient patients for any clinical trial. Inspire may later decide to change the focus of a Phase 3 program. The Phase 3 clinical trials for denufosol for CF may not be successful. Even if such trials are successful, Inspire cannot predict when, or if, the FDA or other regulatory authorities will approve denufosol and allow its commercialization. Further information regarding factors that could affect Inspire's results is included in Inspire's filings with the SEC. Inspire undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof.

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