



Discovery Labs Announces Presentation & Key Results of Phase 2a Study of Aerosolized KL₄ Surfactant in Cystic Fibrosis at the North American Cystic Fibrosis Conference

Warrington, PA – October 22, 2010 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announces that the Phase 2a clinical study of aerosolized KL₄ surfactant (*lucinactant*) in patients with cystic fibrosis (CF) was presented at the *2010 North American Cystic Fibrosis Conference* (NACFC). The trial was conducted as an investigator-initiated study under the direction of Dr. Scott H. Donaldson at The University of North Carolina (UNC) with support from PARI Pharma GmbH, and was funded by Cystic Fibrosis Foundation Therapeutics, Inc., a nonprofit affiliate of the Cystic Fibrosis Foundation.

This study was the first-of-its-kind double-blind, randomized crossover Phase 2a study to evaluate whether Discovery Labs' aerosolized KL₄ surfactant, delivered by an investigational eFlow Nebulizer System (PARI Pharma GmbH, Munich, Germany), is safe and well tolerated in patients (n = 16) with mild to moderate CF lung disease, compared with the active comparator, aerosolized saline control. In addition, the short-term effectiveness of aerosolized KL₄ surfactant was assessed. Key results from the study included:

- Aerosolized KL₄ surfactant delivery appears feasible to CF patients
- Aerosolized KL₄ surfactant was generally safe and well tolerated and was not associated with serious adverse events (SAEs) in this trial
- Aerosolized KL₄ surfactant produced a marked, significant ($p < 0.01$) increase from patient baseline in mucociliary clearance (MCC) measured one hour after the last dose in both whole lung and peripheral lung compartments; however, this effect was not different vs. the active comparator control group at this time point

Dr. Donaldson, Associate Professor of Pulmonary and Critical Care Medicine, University of North Carolina Medical Center and Study Principal Investigator commented, "Cystic fibrosis patients are in desperate need of new therapeutic options and we are encouraged by the results of this Phase 2a trial. The team at UNC envisions a potential complementary therapeutic role for aerosolized KL₄ surfactant, specifically targeting airway mucus adhesion. This trial establishes feasibility of such an approach as well as rationale for further development. Discovery's next-generation lyophilized KL₄ surfactant drug candidate may provide for even further utility through simplified preparation and administration for CF patients."

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs commented, "We are very encouraged with the results from this trial and are pleased that Dr. Donaldson had the opportunity to present trial results at the prestigious NACF Congress. This experience represents the first meaningful assessment of feasibility relating to therapeutic use of

aerosolized KL₄ surfactant in an ambulatory setting. We look forward to continued dialogue with the UNC team and the other collaborators supporting this trial to define next steps.”

CF is caused by a genetic mutation that leads to the production of thick, viscous mucus that is difficult to clear from the airways of the lung. The abnormal mucus allows for chronic airway infections that lead to airway destruction, decreased lung function, and ultimately, death. Previous preclinical and exploratory clinical studies suggest that therapeutic surfactants may improve mucociliary clearance, thereby potentially preventing further compromise of lung function. KL₄ surfactant may be a uniquely advantaged new therapeutic approach in this regard, since it has been demonstrated to be safe and well tolerated in several previous clinical trials and it can be effectively aerosolized.

About the North American Cystic Fibrosis Conference (NACFC)

The NACFC is a scientific conference designed exclusively for medical professionals in the field of CF study and care and is attended by over 3,000 physicians, research scientists, nurses, social workers, nutritionists, dietitians, physical therapists, respiratory therapists, pharmacists, psychologists, psychiatrists and research coordinators. The conference offers more than 70 educational and scientific sessions on the latest CF research and therapies, as well as a showcase of CF-related products and services. Educational topics include the importance of newborn screening, advancements in drug discovery and development, the importance of clinical trials, quality improvement and patient outcomes, comprehensive lung care, and improving nutrition care.

About Cystic Fibrosis (CF)

CF is a fatal genetic disease that causes life-threatening lung infections and premature death. It affects approximately 30,000 patients in the United States and nearly 70,000 worldwide. It is one of the most common genetic disorders in the United States. To date, treatment of pulmonary conditions in CF primarily includes antibiotics to address lung infection and airway clearance therapies to break down and remove mucus. Despite advances in research and medical therapies, the predicted median age of survival for patients with CF in the United States is currently 37 years.

About the Cystic Fibrosis Foundation (CFF)

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, visit www.cff.org.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing KL₄ surfactant therapies for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary KL₄ surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol and lyophilized formulations. In addition, Discovery Labs' proprietary capillary aerosolization technology produces a dense aerosol, with a defined particle size that is capable of potentially delivering aerosolized KL₄ surfactant to the deep lung without the complications currently associated with liquid surfactant administration. Discovery Labs believes that its proprietary technology platform makes it possible, for the first time, to develop a significant pipeline of surfactant products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.com.

Forward Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those related to Discovery Labs' pre-clinical and clinical research and development activities, are described in Discovery Labs' filings with the Securities and Exchange Commission, including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Except as otherwise required by law, Discovery Labs undertakes no obligation to update or revise any forward-looking statements.

Contact Information:

Media relations:

Michelle Linn, Linnden Communications

508-362-3087

Investor relations:

John G. Cooper, President and Chief Financial Officer

215-488-9490