



Discovery Labs' KL₄ Surfactant Granted Orphan Drug Designation in Europe for the Treatment of Cystic Fibrosis

WARRINGTON, PA - November 3, 2011 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)** today announced that the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) has granted orphan drug designation to Discovery Labs' KL₄ surfactant for the treatment of cystic fibrosis (CF). Orphan designation provides for up to ten years of market exclusivity in the European Union (EU) for the drug product with the designated orphan indication. This period of market exclusivity initiates upon EU marketing authorization.

Dr. Thomas F. Miller, Discovery Labs' Chief Operating Officer commented, "Discovery Labs has successfully procured orphan designations for several respiratory disease targets for our KL₄ surfactant. We now have successfully secured orphan designations for CF treatment in both the U.S. and Europe. Our development experience to date suggests that CF may be a viable therapeutic target for our aerosolized KL₄ surfactant technology."

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. Last year, Discovery Labs announced the completion of an investigator-initiated, double-blind, randomized crossover Phase 2a study that evaluated the safety, tolerability and effectiveness of aerosolized KL₄ surfactant in a CF patient population. The trial results were presented at the 2010 North American Cystic Fibrosis Conference, and the principal investigator concluded that aerosolized KL₄ surfactant delivery to CF patients was feasible, was generally safe and well-tolerated, and was not associated with serious adverse events.

About Orphan Designation (US and EU)

Orphan designation by the EMA is intended to encourage sponsor development of new therapeutics for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the EU for which there is no satisfactory method of diagnosis, prevention or treatment of the condition at time of market authorization. Receipt of an orphan designation by EMA qualifies the sponsor for up to ten years of marketing exclusivity following marketing authorization, as well as other sponsor incentives including reduction in certain fees typically associated with the drug product review process in the EU. The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. Orphan drug designation in the United States is awarded to compounds that offer potential therapeutic value in the treatment of rare diseases, defined as those affecting fewer than 200,000 Americans. If a sponsor complies with certain FDA specifications and receives marketing approval for the designated indication, orphan drug designation qualifies the sponsor for up to seven years of marketing exclusivity upon US marketing authorization, tax credits related to clinical research, and an exemption from Prescription Drug User Fee Act filing fees.

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 Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to create life-saving products for critical care patients with respiratory disease and improve the standard of care for pulmonary medicine. 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, lyophilized and aerosol formulations. Discovery Labs is also developing its proprietary drug delivery technologies – capillary aerosol generator and novel patient interface adapters – to enable efficient, targeted upper respiratory or alveolar delivery of aerosolized KL₄ surfactant. Discovery Labs believes that its proprietary technology 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 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.

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