



New Data Shows Surfaxin[®] Survival Benefit Continues Through One Year of Life

Data Presented as a Late-Breaker at the 2005 Pediatric Academic Societies' Annual Meeting

Warrington, PA - May 18, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announced that additional long-term clinical data from their two Surfaxin[®] (lucinactant) Phase 3 clinical trials to treat Respiratory Distress Syndrome (RDS) in premature infants, SELECT and STAR, were presented by Fernando Moya, M.D., Chair of the SELECT study Steering Committee, as a late-breaker presentation at the *Pediatric Academic Societies' Annual Meeting* held in Washington D.C. In his presentation, Dr. Moya reported that premature infants treated with Surfaxin experienced a survival benefit through one year of life, corrected age compared to those treated with the currently available animal-derived surfactants (Survanta[®] and Curosurf[®]). These findings build upon the statistically significant pooled data that was presented at the December 2004 *Hot Topics in Neonatology Meeting*, which demonstrated that premature infants treated with Surfaxin experienced a survival benefit at 36 weeks post-menstrual age versus animal-derived surfactants.

The additional long-term clinical data were derived from a pooled analysis that combined data from the SELECT and STAR trials. This analysis was performed to determine the long-term outcomes including mortality and morbidity at one year of life, corrected age for Surfaxin versus the leading animal-derived surfactants, Survanta and Curosurf. The pooled Surfaxin data showed significantly ($p=0.05$) improved survival compared to the combined data from the two animal-derived surfactants (Survanta and Curosurf).

“The long-term outcomes from the pooled analysis are particularly important because they suggest that a next-generation surfactant therapy, such as Surfaxin, may save more babies’ lives while improving their chances for a healthy future,” said Fernando Moya, M.D., Chair of the SELECT study Steering Committee and Richard W. Mithoff Professor of Neonatal-Perinatal Medicine, Department of Pediatrics UT-Houston School of Medicine. “Premature infants are a population with uncertain long-term outcomes. Any additional long-term benefits that can be achieved while increasing their odds for survival, such as reduced complications associated with BPD, represent a significant advancement in neonatal care.”

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents a potential alternative for the animal-derived and non-protein containing synthetic surfactants. Discovery’s Surfaxin has recently received an Approvable Letter from the United States Food and Drug Administration (FDA) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and is pending approval.

At the same medical congress, Dr. Melpo Christofidou-Solomidou, from the University of Pennsylvania Department of Medicine, Pulmonary, Allergy and Critical Care Division, presented a preclinical study indicating that KL-4 surfactant (Surfaxin) provides a unique anti-inflammatory benefit relative to Survanta, the current US market leader.

Dr. Christofidou-Solomidou, commented, “Discovery’s surfactant exhibited a significant reduction in protein leak and influx of inflammatory cells into the airways versus the comparator surfactant. These

data suggest that Surfaxin may behave differently than currently available surfactants at the cellular level. These comparative results are very intriguing.”

About The Pediatric Academic Societies’ Annual Meeting

The Pediatric Academic Societies (PAS) consists of the American Pediatric Society, the Society for Pediatric Research and the Ambulatory Pediatric Association. The PAS annual meeting is recognized as the largest, most prestigious meeting dedicated to pediatric research and education in the world and brings together physicians with expertise in all areas of pediatrics. More than 5,000 pediatric healthcare providers, including approximately 1,100 neonatologists attend.

About Discovery Labs

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery’s technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to be developed into a series of respiratory therapies for patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has received an Approvable Letter from the FDA for Surfaxin, the Company’s lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term infants.

More information about Discovery is available on the Company's Web site at www.DiscoveryLabs.com.

To the extent that statements in this press release are not strictly historical, including statements as to business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of Discovery’s product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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. Among the factors which could affect Discovery’s actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery’s research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery’s internal sales and marketing organization will not succeed in developing market awareness of Discovery’s products, risk that Discovery’s internal sales and marketing organization

will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery's clinical studies, and risks relating to the development of competing therapies and/or technologies by other companies. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from tests are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Those associated risks and others are further described in Discovery's 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.

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