



Discovery Labs Presents Surfaxin[®] Data at Pediatric Academic Societies Annual Meeting

Warrington, PA - May 7, 2008 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, announced that SURFAXIN[®] pre-clinical and clinical data were presented at the *Pediatric Academic Societies Annual Meeting*. The *Pediatric Academic Societies* annual meeting is internationally recognized as the largest, most relevant medical meeting dedicated to pediatric research.

The following studies were presented:

SURFAXIN[®] (lucinactant) Significantly Attenuates Inflammation and Preserves Lung Structural Integrity vs. Animal-derived Surfactants in a RDS Model: *Marla R. Wolfson, et al.*

In a preclinical study that utilized a well-established animal model of Respiratory Distress Syndrome (RDS), pre-terms lambs were randomized to receive, by intratracheal instillation, either SURFAXIN[®] (lucinactant), Survanta[®] (beractant), Curosurf[®] (poractant alfa), or no surfactant replacement therapy. Measurements of lung function were performed immediately before and for the four hour period following surfactant administration. Blood and lung samples were collected to measure the presence of inflammatory mediators as well as to examine the structural integrity of the lung. The objective of the study was to assess the effect of SURFAXIN[®] on biomarkers of lung inflammation and lung structure in mechanically ventilated very preterm lambs and to compare these outcomes to those treated with animal-derived surfactants or no surfactant replacement therapy.

The results of the study showed that lambs treated with SURFAXIN[®] had better lung function compared with lambs treated with either Survanta[®], Curosurf[®], or no surfactant replacement as demonstrated by a sustained oxygenation response ($p < 0.05$) and a lower ventilatory pressure requirement ($p < 0.05$). In addition, lambs treated with SURFAXIN[®] had better structural integrity, as assessed by evaluation of lung tissue ($p < 0.05$) and lower levels of lung tissue and blood inflammatory mediators ($p < 0.05$) compared with lambs treated with Survanta[®] or no surfactant replacement therapy.

This study, funded by Discovery Labs, was conducted under the direction of Dr. Marla R. Wolfson, Associate Professor, Departments of Pediatrics and Physiology at Temple University School of Medicine in Philadelphia, PA. The pre-term RDS lamb model was selected because it closely resembles the development, structure, and function of human lungs and is the most relevant system to study the pathophysiology and treatment of RDS.

Successful Rapid Extubation to nCPAP Following Surfactant Treatment Does Not Depend on Surfactant Preparation: *Jan Mazela, et al.*

The current standard treatment for premature infants with RDS typically requires that the infant is intubated to allow mechanical ventilation and surfactant administration. If therapy is successful,

extubation occurs when the infant can spontaneously breathe without ventilatory support. Multiple clinical investigations are underway to assess the potential value of rapidly extubating infants with RDS following surfactant administration to determine whether reducing intubation time impacts complications of prematurity.

This study analyzed a subset of 148 infants from the SELECT Trial (Discovery's pivotal Phase 3 clinical trial for SURFAXIN[®] for the prevention of RDS in premature infants). The post-hoc analysis was based on a prospectively defined patient population with pre-specified outcomes measures. The objective of the analysis was to determine the rate of successful rapid extubation following surfactant treatment among infants treated with different surfactants.

Overall, the trends for the success of extubation at both 7 and 28 days of life and 36 weeks post-conceptual age (PCA) all favored SURFAXIN[®] relative to the comparator surfactants, although these results did not achieve statistical significance. The study concluded that rapid extubation following surfactant treatment can be successfully implemented regardless of the type of the surfactant administered.

Robert Segal, M.D., Senior Vice President and Chief Medical Officer of Discovery Labs, commented, "The current treatment approach for babies with RDS requires delivery of surfactants via an endotracheal tube and mechanical ventilation. Mechanical ventilation and supplemental oxygen lead to acute inflammatory responses which may cause bronchopulmonary dysplasia (BPD), also known as chronic lung disease. These data suggest that early intervention with SURFAXIN[®] may mitigate the progression of RDS to BPD. We intend to continue to support research that tests this hypothesis."

About SURFAXIN[®]

SURFAXIN[®], an investigational drug, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. The presentations listed above include information that may be of interest to healthcare practitioners; however, the clinical relevance of this information has not been established.

SURFAXIN[®] is a peptide-containing synthetic surfactant that is structurally similar to pulmonary surfactant, a substance produced naturally in the lungs and essential for breathing. SURFAXIN[®] is based on the novel KL-4 peptide. KL-4 is a 21-amino acid peptide with structural similarities to pulmonary surfactant protein B (SP-B), the surfactant protein most important for normal respiratory function.

SURFAXIN[®] is also being developed for the prevention and treatment of bronchopulmonary dysplasia (BPD), a debilitating and chronic lung disease typically affecting premature infants who have suffered RDS, and the treatment of Acute Respiratory Failure (ARF) in children up to two years of age.

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 scientists and physicians with expertise in all areas of pediatrics. More than 5,000 pediatric healthcare providers, including approximately 1,100 neonatologists attend this meeting annually.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a peptide-containing synthetic surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that, with its proprietary technology, SRT has the potential, for the first time, to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs' lead product candidate, SURFAXIN[®], is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. SURFAXIN[®] is also being developed for other neonatal and pediatric indications. AEROSURF[™], Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at www.Discoverylabs.com.

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, including, without limitation, the risks that: Discovery Labs may be unable to timely respond, if at all, to the recent approvable letter; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of a drug product or may withhold, delay and/or limit marketing of a drug product by indication or impose other label limitations; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of drug products; Discovery Labs may be unable to profitably develop and market its products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may be unable to successfully manufacture or provide adequate supplies of drug substances on a timely basis; Discovery Labs may be unable to transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; Discovery Labs and its collaborators may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs' drug products with innovative aerosolization technologies; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further 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.

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