Newly-Published Study Compares SURFAXIN LS™ and CUROSURF® in Well-Established Model of Respiratory Distress Syndrome

Warrington, PA — May 08, 2012 — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, reported that data from a preclinical study of SURFAXIN LS™ (lyophilized KL₄ surfactant) was recently published in the May issue of Pediatric Research. The results of the study demonstrate that improvements in lung function following administration of SURFAXIN LS compares favorably to improvements in lung function following administration with Curosurf®. In addition, physiologic findings suggest that SURFAXIN LS may have a more favorable safety profile at the time of surfactant administration. The study was conducted in the preterm lamb model of surfactant deficiency, a preclinical model recognized by the neonatal academic community as a well-established surrogate for human respiratory distress syndrome (RDS). Curosurf is the current global, market-leading, animal-derived surfactant. SURFAXIN LS, is being developed as a lyophilized dosage form of SURFAXIN®, the first synthetic, peptide-containing surfactant approved by the U.S. Food and Drug Administration (FDA) for use in neonatal medicine.

The objective of the study was to compare the effects of SURFAXIN LS and Curosurf on pulmonary function, as well as the physiologic reactions to surfactant administration in preterm lambs with RDS. The results of this study, which were previously presented to the 2010 Pediatric Academic Societies Annual Congress in May 2010 include:

- Both surfactants significantly improved pulmonary function (p < 0.05). However, lambs treated with SURFAXIN LS required significantly lower mechanical ventilator pressures to maintain pulmonary function compared with Curosurf-treated lambs (p < 0.05).

- In contrast to lambs treated with SURFAXIN LS, lambs treated with Curosurf experienced significant reductions in heart rate and rapidly increased brain oxygenation during the peridosing period (p < 0.05).

- The investigators concluded that SURFAXIN LS may enable ventilation at lower mean airway pressures, thereby potentially reducing the incidence of chronic lung disease, and as such may be an effective substitute for the currently-marketed surfactant products.

Dr. Russell G. Clayton, Senior Vice President, Research & Development of Discovery Labs commented, “The observations in this study suggest that SURFAXIN LS may reduce potentially unfavorable responses to surfactant administration. These study results, when combined with the anticipated flexibility and ease of use benefits, suggest that SURFAXIN LS potentially represents a meaningful improvement in this class of drugs.”

On March 6, 2012, the FDA granted marketing approval for SURFAXIN (lucinactant) for the prevention of RDS in premature infants at high risk for RDS. SURFAXIN provides U.S. healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. While SURFAXIN is stored and delivered in a liquid dosage form, SURFAXIN LS is stored as a powder and re-suspended to liquid form prior to use, eliminating the need for refrigerated storage. Discovery Labs is implementing a development plan intended to gain marketing authorization for SURFAXIN LS in the U.S., the European Union and other major markets worldwide.
Dr. Clayton continued, “Our development strategy for SURFAXIN LS is to build upon the SURFAXIN clinical experience and advance a dosage form that will improve ease of use of surfactant administration for healthcare practitioners, as well as potentially prolong shelf life and eliminate the need for a temperature-controlled supply chain. We look forward to continued advancement of this important program, with the goal of initiating our clinical program in the second half of 2013.”

About Pediatric Research

Pediatric Research presents the work of leading authorities in pediatric pulmonology, neonatology, cardiology, hematology, neurology, developmental biology, fetal physiology, endocrinology and metabolism, gastroenterology, and nutrition. Directed to research-oriented pediatricians and faculty, the journal publishes the results of significant clinical and laboratory studies. The Journal includes original peer-reviewed articles, abstracts of society meetings, state-of-the-art reviews, as well as supplements on pediatric health issues. Pediatric Research is the official publication of the American Pediatric Society, the European Society for Paediatric Research, and the Society for Pediatric Research.

The study will be published in the April 2012 issue of Pediatric Research under the following title:

Comparison of poractant alfa and lyophilized lucinactant in a preterm lamb model of acute respiratory distress

Jan Mazela, T. Allen Merritt, Michael H. Terry, Timothy J. Gregory & Arlin B. Blood

IMPORTANT SAFETY INFORMATION

SURFAXIN (lucinactant intratracheal suspension) is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted and the infant’s clinical condition assessed and stabilized. SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS).

For more information about SURFAXIN, please visit www.surfaxin.com.

SURFAXIN LS is an investigational drug product and is not approved for use.

About Discovery Labs

Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to advance a new standard in respiratory critical care. Discovery Labs’ novel proprietary KL₄₄ surfactant
technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized, and aerosolized dosage forms. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient delivery of aerosolized KL4 surfactant and other inhaled therapies. Discovery Labs believes that its proprietary technologies make it possible, for the first time, to develop a significant pipeline of 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 activities and Discovery Labs’ development strategy for, and expectations with respect to, its SURFAXIN LS development plan, 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.

**Contact Information:**
Media relations:
Michael Parks, Pitch360 Incorporated
michael@pitch360inc.com
484.356.7105

Investor relations:
John G. Cooper, President and Chief Financial Officer
215.488.9490