



## DISCOVERY LABORATORIES, INC.

### **Pivotal Phase 3 Study Results of Surfaxin<sup>®</sup> (lucinactant) for the Prevention of Respiratory Distress Syndrome in Premature Infants to be Presented at the Pediatric Academic Societies' Annual Meeting**

**Doylestown, PA — April 27, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**

announced today that lead study investigators will be presenting results from two Phase 3 clinical trials of Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants during the Pediatric Academic Societies' (PAS) Annual Meeting in San Francisco, May 1-4. Surfaxin is a novel, peptide-containing, humanized lung surfactant developed from Discovery's proprietary surfactant replacement technology platform. RDS in premature infants is a major, costly breathing disorder with significant mortality and morbidity.

Surfaxin study results from the landmark superiority and non-inferiority clinical trials to be presented at the PAS Annual Meeting include:

- *Superiority of a Novel Surfactant, Surfaxin<sup>®</sup> (lucinactant), over Exosurf<sup>®</sup> (colfosceril palmitate) in Preventing Respiratory Distress Syndrome in Very Pre-term Infants:* presented by Fernando Moya, MD on Sunday, May 2 at 4:30-4:45 pm PST in room 2004-6-8 at the Moscone West Convention Center
- *Randomized, Controlled Trial of a New Generation Surfactant, Surfaxin<sup>®</sup> (lucinactant), Versus Curosurf<sup>®</sup> (poractant alfa) for the Prevention and Treatment of RDS in Very Pre-term Infants:* presented by Sunil Sinha, MD on Sunday, May 2 at 4:45-5:00 pm PST in room 2004-6-8 at the Moscone West Convention Center

In addition, the following poster will be presented:

- *Comparison of the Novel Lung Surfactant Surfaxin<sup>®</sup> (lucinactant) with Currently Available Commercial Products:* presented by Michael Nutt, PhD on Tuesday, May 4, at 12:00-1:30 pm PST; Poster #136 on Level 1 Exhibit Hall of the Moscone West Convention Center

Earlier this month, Discovery submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for clearance to market Surfaxin for the prevention of RDS in premature infants. The NDA filing was supported, in large part, by data from Discovery's two Phase 3 RDS clinical trials.

Discovery also is preparing a Marketing Authorization Application (MAA) to be filed with the European Medicines Evaluation Agency (EMA) by the middle of 2004 for Surfaxin for the prevention and treatment of RDS. Recently, the Committee for Proprietary Medicinal Products (CPMP) determined that Surfaxin qualified for evaluation through the Centralized Procedure, a more streamlined European regulatory review process that allows for a single application, evaluation and authorization for the entire European Union.

## **Surfaxin – an engineered surfactant with the potential to address RDS worldwide**

Surfactants are substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen and to maintain proper airflow through the respiratory system.

Premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS. The current standard of care for treating these patients is Surfactant Replacement Therapy using animal-derived surfactants. Animal-derived products are prepared using a chemical extraction process from cow and pig lung washes or from the mincing of these animal lungs. Because of the inherent limitations of animal-derived products, the manufacture of large quantities of high quality product can be problematic and their use is largely limited to North America and Western Europe.

Discovery's Surfaxin is an engineered version of human lung surfactant and contains a peptide, sinapultide that is designed to closely mimic the activity of essential human lung surfactant protein B (SP-B). Surfaxin, unlike the animal products, can be produced in virtually unlimited quantities, in consistent pharmaceutical grade quality, and has no risk of potential transmission of animal-associated diseases.

## **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 are expected to attend.

## **About Discovery Laboratories**

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases. Surfactants are compositions produced naturally in the lungs and essential for breathing. Discovery's technology produces an engineered version of natural human lung surfactant that is designed to closely mimic the essential properties of 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 critical care and other hospitalized patients where there are few or no approved therapies available.

Discovery has filed a New Drug Application with the United States Food and Drug Administration for clearance to market Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is also conducting a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, Phase 3 and Phase 2 clinical trials for Meconium Aspiration Syndrome in full-term infants and (with aerosolized surfactant) is preparing to initiate a Phase 2 trial for asthma (development name DSC-104) and a Phase 2 trial for Respiratory Dysfunction in premature infants.

*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 the Company's product development, events conditioned on stockholder or other approval, or otherwise as to future events, such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The forward-looking statements contained in this release 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 the Company's actual results and could cause results to differ from those contained in the forward-looking statements contained herein are the risk that financial conditions may change, risks relating to the progress of the Company's research and development, the risk that the Company 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 of delay in the Company's preparation and filing of applications for regulatory approval, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with adequate supplies of drug substance and drug products for completion of any of the Company's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of the Company'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 the Company'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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