



## **DISCOVERY LABORATORIES, INC.**

### **Discovery Laboratories Files New Drug Application with the FDA to Market Surfaxin<sup>®</sup> for the Prevention of Respiratory Distress Syndrome in Premature Infants**

**Doylestown, PA —April 14, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)** today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration for clearance to market Surfaxin<sup>®</sup> for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Surfaxin is a novel, peptide-containing, humanized lung surfactant developed from Discovery's proprietary surfactant replacement technology platform.

The NDA filing is supported, in large part, by data from Discovery's two positive Phase 3 RDS clinical trials. The first was a landmark, 1294 patient pivotal study that demonstrated Surfaxin's superiority to Exosurf<sup>®</sup>, a non-protein containing synthetic surfactant. Survanta<sup>®</sup>, a cow-derived surfactant and the leading surfactant used in the United States, served as a reference arm in the trial. The second trial was a 252 patient supportive study that demonstrated Surfaxin's non-inferiority to Curosurf<sup>®</sup>, a pig-derived surfactant and the leading surfactant used in Europe.

Christopher J. Schaber, Ph.D., Discovery's Executive Vice President and Chief Operating Officer commented, "We have submitted a high quality data package to the FDA that we believe demonstrates the benefit of Surfaxin for the prevention of RDS in these very premature babies. This accomplishment is due to the tremendous efforts of the entire Discovery team and the dedication of our clinical investigators and advisors. We now look forward to productive interactions with the FDA to facilitate a timely and thorough review of our NDA. RDS is an extremely devastating disease. We believe that Surfaxin, if approved, would set a new standard for the prevention of RDS."

Detailed results from the Surfaxin Phase 3 clinical trials will be presented by leading study investigators in May at the 2004 annual meeting of the Pediatric Academic Society (PAS) in San Francisco. Specific meeting and presentation details will be released in an upcoming communiqué.

Discovery is also 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 natural human lung surfactant and contains a peptide, sinapultide, that is designed to closely mimic the 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 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 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 amendments thereto.*

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