



## **SURFAXIN<sup>®</sup> Receives Orphan Drug Designation from European Commission**

**Doylestown, PA — August 12, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced that the Commission of the European Communities has designated Surfaxin<sup>®</sup> as an Orphan Medicinal Product. This designation is for the prevention of Respiratory Distress Syndrome (RDS) in premature neonates of less than 32 weeks of gestational age and for the treatment of RDS in premature neonates of less than 37 weeks of gestational age. Designation was granted following the positive opinion given by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Evaluation Agency (EMA) in which the COMP concluded that although satisfactory methods of prevention and treatment of RDS have been authorized in Europe, justifications have been provided that Surfaxin may be of significant benefit to those at risk of developing or affected by the condition.

The EMA grants orphan drug designation to medicinal products based upon several criteria: the life-threatening and debilitating nature of the condition; the medical plausibility of the proposed orphan indication; a prevalence in Europe of less than 5 cases for each 10,000 of population; and the lack of a satisfactory method of diagnosis, prevention or treatment or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition.

This designation allows Discovery exclusive marketing rights for Surfaxin in the indication of RDS in Europe for ten years (subject to revision after six years) following marketing approval by the EMA. In addition, the designation enables Discovery to receive regulatory assistance in the further development process of the drug, and to access reduced regulatory fees throughout its marketing life.

Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer of Discovery, stated, "The granting of Orphan Medicinal Product designation together with the United States FDA's acceptance of the Surfaxin NDA, increases our confidence in the potential for Surfaxin to become a new, worldwide standard of care for the prevention and treatment of RDS. Market exclusivity under this designation would equate to Surfaxin becoming the only engineered surfactant available in Europe. With this designation and our existing patent portfolio, we believe Surfaxin has the potential to become the dominant engineered surfactant for the next decade and thereby block any future similar products for the treatment and prevention of RDS throughout the European market."

The United States Food and Drug Administration (FDA) has already granted orphan drug designation for Surfaxin for the prevention of RDS in premature infants. Recently the FDA accepted Discovery's New Drug Application for Surfaxin for the prevention of RDS in premature infants and has granted a PDUFA date of February 13, 2005. Discovery also is preparing a Marketing Authorization Application (MAA) to be filed with the EMA for Surfaxin for the prevention and treatment of RDS.

### **Respiratory Distress Syndrome in Premature Infants**

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 FDA for clearance to market Surfaxin<sup>®</sup>, the Company's lead product, for the prevention of Respiratory Distress Syndrome in premature infants. Discovery is currently 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. With aerosolized surfactant formulations, Discovery 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.

More information about Discovery is available on the Company's Web site at [www.DiscoveryLabs.com](http://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 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, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by the Company, 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 the Company for any such drug*

*product, 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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