



Discovery Labs' Surfaxin[®] Granted Orphan Drug Designation for the Treatment of Bronchopulmonary Dysplasia

Warrington, PA, October 28, 2005 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)**, today announced that the Office of Orphan Products Development of the United States Food and Drug Administration (FDA) has granted orphan drug designation to Discovery's lead product, Surfaxin[®], for the treatment of Bronchopulmonary Dysplasia (also known as Chronic Lung Disease, CLD) in premature infants. Surfaxin, a precision-engineered lung surfactant replacement therapy, has received an Approvable Letter from the U.S. FDA for the prevention of Respiratory Distress Syndrome (RDS) in premature infants and is pending approval.

CLD is a costly syndrome associated with surfactant and SP-B deficiency, and the prolonged use of mechanical ventilation and oxygen supplementation, usually associated with a premature infant being treated for RDS. Presently there are no approved drugs for the treatment of CLD. These babies suffer from abnormal lung development and typically have a need for respiratory assistance - oftentimes, for many months, as well as comprehensive care that sometimes can span many years.

The U.S. Orphan Drug Act is intended to assist and encourage companies to develop safe and effective therapies for the treatment of rare diseases and disorders. Orphan drug designation in the United States is awarded to compounds that offer potential therapeutic value in the treatment of rare diseases, defined as those affecting fewer than 200,000 Americans. If the company complies with certain FDA specifications and should the drug receive marketing approval, orphan drug designation qualifies the sponsor for seven years of marketing exclusivity, exemption from the Prescription Drug User Fee Act (PDUFA) filing fees, and tax credits related to clinical research.

Robert J. Capetola, Ph.D. President and Chief Executive Officer of Discovery commented, "Market exclusivity under this designation would mean that Surfaxin, as a precision-engineered surfactant, has the potential to become the dominant engineered surfactant for the next decade. If Surfaxin is the first product to receive marketing authorization in the United States for the treatment of Bronchopulmonary Dysplasia, orphan status would block any future similar products for this indication throughout the United States market for a prolonged period of time."

Discovery is currently conducting a Phase 2 double-blind, controlled trial (that will enroll up to 210 very low birth weight premature infants born at risk for developing CLD) to determine the safety and tolerability of administering up to 5 total doses of Surfaxin in the first 10 days of life as a therapeutic approach for the prevention and treatment of CLD. This study is designed to determine whether such treatment can decrease the proportion of infants on mechanical ventilation or oxygen or the incidence of death or CLD.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant. Discovery's Surfaxin has received an Approvable Letter from the FDA for the prevention of RDS in premature infants and is pending approval. 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.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery believes that through its technology, pulmonary surfactants have the potential, for the first time, to address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the prevention and treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is in development to address neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

For more information, please visit our corporate website at 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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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. Among the factors which could affect Discovery's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery 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 that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, 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 Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of

adequate supplies of drug substance and drug product for completion of any of Discovery'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 Discovery'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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