



DISCOVERY LABORATORIES, INC.

FDA Selects Discovery Laboratories' Surfaxin[®] ARDS Program For Its New Continuous Marketing Application Pilot 2 Program

Doylestown, PA — February 19, 2004 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary humanized surfactant technology as Surfactant Replacement Therapies for respiratory diseases, today announced that the U.S. Food and Drug Administration has selected Surfaxin[®] for the treatment of Acute Respiratory Distress Syndrome (ARDS), as the only applicant within the Division of Pulmonary and Allergy Drug Products to be included in its Continuous Marketing Application (CMA) Pilot 2 Program. Participation in this initiative is limited to one Fast Track product for each review division within the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) over the course of the program.

The Pilot 2 program was established to study and document the benefits of more frequent FDA feedback and interactions as a company moves through the various phases of development, with the goal that such interactions will expedite the development of Fast Track products.

“We are gratified to have been selected for this innovative program. Given the devastating effects of ARDS both in terms of mortality and disease-related complications, inclusion into this program is an opportunity to collaborate closely with the FDA in defining the scope of the development program and endpoints to capture the essence of surfactant replacement therapy for these patients,” said Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery. “We look forward to an increased level of scientific exchange and interaction with the FDA to ensure a high quality ARDS program and agreed upon path toward approval.”

The objective of the Pilot 2 program is to evaluate the costs and benefits of enhanced sponsor access to guidance and feedback from the FDA during the Investigational New Drug (IND) phase of new drug development of Fast Track products and determine whether such activity can improve the efficiency of the drug development and review process. Once selected, participants in the Pilot 2 program and the FDA define specific agreements on the nature and timing of feedback and interactions between the participants and the FDA. Eligibility is limited to drug and biological products that have Fast Track designation and have been subject to an end of phase 1 clinical trial or equivalent meeting. Criteria for selection included the FDA's assessment of the potential value of enhanced interaction with an emphasis on the health benefits likely to result from successful drug development. For more information on CMA Pilot 2, visit <http://.fda.gov/cder/guidance/5740-fnl.pdf>.

About Acute Respiratory Distress Syndrome

ARDS is a life-threatening respiratory disorder for which there are currently no approved therapies anywhere in the world. It is estimated that there are between 150,000 and 250,000 ARDS patients per year in each of the U.S. and Europe. The mortality rate can range from 35%

to 50%. The current standard of care includes placing patients on mechanical ventilators in intensive care units at an average estimated cost of approximately \$8,500 per day typically for an average of 21 to 28 days. One prominent characteristic of ARDS is the destruction of the lung's natural surfactant that is essential to the ability to absorb oxygen. ARDS is also characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient's blood. These conditions are caused by events such as pneumonia, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents, sepsis and other traumas.

About Discovery Laboratories

Discovery Laboratories, Inc. is a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases including Respiratory Distress Syndromes in infants and adults, Acute Lung Injury, asthma, Chronic Obstructive Pulmonary Disease and upper airway disorders. 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 provide 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 recently completed two Phase 3 clinical trials of Surfaxin[®], the Company's lead product, for the treatment of Respiratory Distress Syndrome in premature infants and is preparing to file new drug applications with the Food and Drug Administration and other regulatory authorities in the rest of the world. Discovery's Surfactant Replacement Therapy is also in a Phase 2 clinical trial for Acute Respiratory Distress Syndrome in adults, a Phase 3 and a Phase 2 clinical trial for Meconium Aspiration Syndrome in full-term infants, and a Phase 1b clinical trial for asthma.

More information about Discovery is available on the Company's Web site 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 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), risks relating to the progress of the Company's research and development, risks relating to the ability of the Company's third party contract manufacturers to provide the Company with sufficient amounts of drug products for completion of any of the Company's clinical studies, other risks relating to the lack of sufficient 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-KSB, 8-K, 10-Q and 10-QSB, and amendments thereto.

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