



DISCOVERY LABORATORIES, INC.

Discovery Laboratories Initiates Phase 1b Asthma Clinical Trial

Doylestown, PA — December 22, 2003 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies for respiratory diseases, has initiated a Phase 1b clinical trial to evaluate the safety and tolerability of its humanized lung surfactant, delivered as an inhaled aerosol, to treat hospitalized patients who suffer from asthma.

Discovery recently received CTX clearance from the Medicines and Healthcare products Regulatory Agency (MHRA) to initiate this clinical trial in the United Kingdom. The clinical trial is a masked, placebo-controlled, randomized, dose-escalation study that is being conducted at a leading pulmonary research facility. The primary study objective is to assess preliminary safety and tolerability, as well as to establish the deposition characteristics of Discovery's aerosolized formulation of its surfactant therapy in healthy subjects and mild-persistent asthmatic patients. The initial arm of the study which included 6 healthy subjects has been completed. The second study arm is ongoing and will include up to 12 mild asthmatic patients.

Asthma is a common disease characterized by sudden constriction and inflammation of the lungs. Constriction of the upper airway system occurs when airway muscles tighten, while inflammation is a swelling of the airways usually caused by an allergic reaction from an airborne irritant. Both of these events cause airways to narrow and may result in wheezing, shortness of breath and chest tightness.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery commented, "During an asthmatic episode, surfactant damage and dysfunction occurs in the airways of the deep lung and those airways become obstructed. Several scientific studies report that patients suffering from a severe, acute asthma attack were relieved when they inhaled aerosolized surfactant. We believe that our humanized Surfactant Replacement Therapy as an aerosol spray has the potential of relieving the obstruction in the airways associated with asthma. This Phase 1b study will be completed early in the first quarter of 2004 and, if the results support it, we look forward to initiating a U.S.-based Phase 2 study mid-year."

Asthma may require life-long therapy. Ten percent of patients are considered severe asthmatics and require moderate to high doses of drugs. Currently available asthma medications include inhaled and oral steroids and bronchodilators. Bronchodilators cannot be used to control severe episodes or chronic, severe asthma. Steroids can cause serious side effects when used for prolonged periods and are typically limited to severe asthmatic episodes and chronic, severe asthma. Discovery believes that supplying surfactant as an aerosol spray may relieve airway obstruction in the deep lung and lead to a more rapid improvement in asthmatic symptoms.

The American Lung Association reports that in 2001 asthma afflicted approximately 20.3 million people in the United States and its incidence rate continues to rise. Asthma ranks within the top 10 prevalent activity-limiting health conditions costing \$14 billion in United States healthcare costs annually.

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 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 recently completed Phase 3 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 United States 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 Laboratories 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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