



DISCOVERY LABORATORIES, INC.

Discovery Laboratories Updates Progress of Pivotal, Landmark Phase 3 Clinical Trial for Respiratory Distress Syndrome in Premature Infants

Doylestown, PA – February 20, 2003 - Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty pharmaceutical company leveraging its technology in humanized lung surfactants to develop novel respiratory therapies, announced today that it anticipates completing and announcing the results from its pivotal, landmark multinational Phase 3 clinical trial for Surfaxin[®] for Respiratory Distress Syndrome (RDS) in premature infants in October 2003, approximately four months later than originally communicated, with the New Drug Application to be filed with the FDA shortly thereafter.

The Company currently has 50 sites enrolling patients worldwide that comply with the Company's rigorous clinical site qualification processes and criteria necessary to participate in this pivotal, landmark clinical trial. Several additional sites were due to be added to the Company's existing qualified clinical trial site base by March 2003. Activating these additional sites was expected to position the Company to complete the landmark trial in May 2003. However, the Company's management decided not to include these substandard sites into its existing base of qualified clinical sites. This decision was reached after a thorough evaluation, and is consistent with the Company's stringent clinical site quality processes and criteria designed to provide the highest probability of success in this pivotal clinical trial to allow the introduction of the first humanized lung surfactant to market.

Based on a reevaluation and allowing for the Company's quality assurance and quality control activities, the Company's existing base of 50 qualified clinical sites should enroll and treat patients at a rate to announce results in October 2003. This landmark clinical trial is currently being conducted in Poland, Hungary, Mexico, Chile, Russia and Brazil, with Uruguay and Panama upcoming.

This pivotal, landmark clinical trial is to be conducted on approximately 1,500 patients and was designed as an event-driven, prophylaxis, superiority trial comparing the Company's lead product, Surfaxin, to an already approved surfactant, Exosurf[®]. Surfaxin is an engineered version of natural human lung surfactant and contains a humanized peptide, sinapultide, that is designed to precisely mimic the essential human lung surfactant protein B (SP-B). Exosurf, although the first approved synthetic surfactant, lacks any surfactant proteins, most noticeably protein SP-B. As a result, it is perceived to be inferior to other commercially available surfactants and its use is largely limited to outside of the U.S. and Western Europe. Survanta[®], the leading animal-derived product in the U.S., will serve as a reference arm in the landmark clinical trial. Survanta is made as an organic extract of bovine lung and contains some surfactant protein; however, its concentration of the essential surfactant protein SP-B can be highly variable and inconsistent.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery stated, “We are convinced of the inherent pharmacology of Surfaxin and its superior profile compared to Exosurf and that the key to success is high quality execution. This landmark, pivotal clinical trial is intended to introduce the first humanized surfactant for respiratory medicine and be the springboard for our surfactant technology to treat a broad range of respiratory diseases. The Company could have made the decision to complete the clinical trial in May 2003; however, to do so would require us to compromise our stringent standards. Accordingly, we choose a course emphasizing quality clinical standards rather than one that would optimize enrollment rates.”

The Company’s procedure for site selection and qualification is quite extensive and consists of a number of critical evaluative steps before a site is allowed to enroll patients in the clinical trial. First, a preliminary evaluation of important medical and clinical conditions is conducted. A candidate site will next undergo on-site training by the Company’s personnel of protocol and corresponding medical practices. Only after satisfactorily completing training, will the candidate site be allowed to engage in controlled, protocol-mandated medical and ventilatory procedures. If the candidate site satisfactorily performs these procedures, the site will be allowed to enroll one to two patients, on a probationary basis, with further evaluation of medical and clinical practices. Only with satisfactory compliance with the foregoing steps, will sites be allowed to commence full patient enrollment activities. Throughout the clinical trial, every site remains under the close scrutiny and supervision of the Company’s medical monitors to ensure compliance with the study’s protocol.

Surfactants are protein/lipid compositions that are produced naturally in the lungs and are critical to the lungs’ ability to absorb oxygen. A lack or deficiency of surfactant is associated with several severe respiratory diseases including respiratory distress syndrome in premature infants (RDS), acute lung injury, acute respiratory distress syndrome, severe asthma, chronic obstructive pulmonary disease, among others. Currently available animal-derived surfactants have been effective in treating premature infants that lack surfactant, but several drawbacks and limitations of these products make it difficult for them to treat broader populations of RDS patients or expand into the broad respiratory disease markets. Because of this, RDS is the only indication for which surfactant products are currently approved. Presently, Discovery is developing the only humanized, engineered version of natural human lung surfactant that can be produced economically in large quantities as a high quality pharmaceutical without the risk of potential transmission of animal-borne diseases or adverse immunological reactions.

About Discovery Laboratories, Inc.

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop a number of potential novel respiratory therapies. Surfactants are produced naturally in the lungs and are essential to the lungs’ ability to absorb oxygen. Discovery’s technology is being developed initially for critical care patients with life-threatening respiratory disorders where there are few or no approved therapies available. Surfaxin, Discovery’s lead product, is currently in Phase 3 clinical trials for Respiratory Distress Syndrome (RDS) in premature infants, a Phase 3 clinical trial for Meconium Aspiration Syndrome (MAS) in full-term infants, and a Phase 2 clinical trial for Acute Respiratory Distress Syndrome (ARDS) in adults. Aerosol formulations are being developed in an effort to treat other respiratory conditions such as asthma, chronic obstructive pulmonary disease, acute lung injury

and upper airway diseases such as sinusitis. Discovery is developing a dedicated sales and marketing capability through a collaboration with Quintiles for the United States, and has a strategic alliance with Esteve for Europe and Latin America. Interested parties can receive corporate updates by sending their email addresses to dsco@focuspartners.com. More information about Discovery Laboratories is available on the Company's Web site at <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 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, risks relating to the progress of the Company's research and development, 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. 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-KSB, 8-K, 10-QSB and 10-Q, and amendments thereto.

Contacts:

John Cooper
CFO/SVP
215-340-4699

ir@discoverylabs.com

FOCUS Partners LLC
Harvey Goralnick/David Zazoff
212-752-9445
dsco@focuspartners.com

###