



DISCOVERY LABORATORIES, INC.

FOR IMMEDIATE RELEASE:

Discovery Laboratories Completes Dose-Ranging Stage of its Phase 2 Clinical Trial of Surfaxin[®] for Acute Respiratory Distress Syndrome (ARDS)

Doylestown, PA — July 18, 2002 — Discovery Laboratories, Inc. (Nasdaq: DSCO), a late-stage specialty pharmaceutical company leveraging its technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products, successfully completed the dose-ranging part of its Surfaxin[®] Phase 2 clinical trial for the treatment of Acute Respiratory Distress Syndrome (ARDS) in adults and is presently enrolling patients in the final part of the trial.

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. ARDS is characterized by an excess of fluid, inflammatory cells and debris in the lungs that leads to decreased oxygen levels in the patient's blood. One prominent characteristic is the destruction of the lung's natural surfactant that is essential to the ability to absorb oxygen. These conditions are caused by events such as pneumonia, aspiration of gastric contents, smoke inhalation, near drowning, industrial accidents, sepsis and other traumas.

The Company's Phase 2 trial is an open-label, controlled, randomized, dose-ranging, multicenter trial comparing the safety and effectiveness of Surfaxin to standard of care. Up to 110 ARDS patients will receive either high dose Surfaxin or the standard of care including mechanical ventilation. Surfaxin will be administered via a proprietary sequential bronchopulmonary segmental lavage technique (a "lung wash" where Surfaxin is delivered through a tube, called a bronchoscope, to each of the 19 to 20 segments of the lung) which is intended to cleanse and remove inflammatory substances from the lungs, while approximately one-half of the Surfaxin remains to help re-establish the lung's capacity to absorb oxygen. The objective is to restore functional surfactant levels in the lung and get critically ill patients off costly mechanical ventilation.

The first part of this trial was a dose escalation safety and tolerability study in 22 patients in four groups (of up to six patients per group). Each group received progressively escalating doses of Surfaxin. The primary endpoints of this part of the trial were safety and tolerability. The Independent Safety Review Committee, comprised of three prominent pulmonologists, reviewed the safety and tolerability data obtained from each of the four dosing groups. In each case, the Committee unanimously agreed to move forward to the next higher dosing group. At the completion of this portion of the trial, both the Company and the Committee determined that the

trial procedure is generally safe and tolerable and that it is appropriate to proceed onto the larger safety and efficacy portion of the trial.

The following table presents summary data of certain key clinical endpoints from the dose-ranging part of the trial:

<i>Patient Group</i>	<i>Number of Patients</i>	<i>Surfaxin Dosage¹</i>	<i>Clinical Results</i>	
			<i>Mortality ((#) and % of Patients)</i>	<i>Average Days On Mechanical Ventilation</i>
<i>A</i>	<i>5</i>	<i>22,800 mg</i>	<i>(3) - 60%</i>	<i>20.8</i>
<i>B</i>	<i>6</i>	<i>34,200 mg</i>	<i>(2) - 33%</i>	<i>17.5</i>
<i>C</i>	<i>6</i>	<i>57,000 mg</i>	<i>(0) - 0%</i>	<i>12.8</i>
<i>D</i>	<i>5</i>	<i>61,000 mg</i>	<i>(0) - 0%</i>	<i>17.2</i>

¹ Based on phospholipid content.

R. Duncan Hite, M.D., Director of Medical Intensive Care and Critical Care Research at Wake Forest University and ARDS Scientific Board Advisor, commented that “Patients with severe ARDS typically require mechanical ventilation in ICUs for an average of three to four weeks, some can require as long as several months. Time on mechanical ventilation is directly associated with adverse patient outcomes and increased cost of care. Reducing ventilator time or ICU stay is a significant benefit to patients as well as to the overall health care system. Surfactant replacement therapy holds great promise in addressing these issues. Although the number of patients in this part of the trial was small, I am encouraged by these results and am hopeful that the results from the larger ongoing Phase II study will be positive. Discovery’s humanized lung surfactant, Surfaxin, and its lavage technique is a logical approach to a surfactant-based therapy for ARDS.”

Timothy J. Gregory, Ph.D., Senior Director of Clinical Development of Discovery and principal architect of Abbott Ross’ ARDS surfactant trials, commented that “based on years of clinical experience with animal-derived surfactants, as reported in published articles, I and others in the field are convinced that surfactant-based therapy can be effective for the treatment of ARDS. However, the limited supply and the excessive cost of animal-derived surfactants precluded further development. With Surfaxin, we can make the considerable quantities necessary to address this indication at a reasonable cost. These advantages are important because the early results in our Phase 2 trial suggest that the most effective dosages are the higher Surfaxin concentrations. In fact, some of the sickest patients were in the high dose groups “C” and “D” and, nevertheless, we experienced the most promising results in these groups.”

The last part of this Phase 2 trial will evaluate safety and efficacy in direct comparison to standard of care in up to 90 additional patients at approximately 30 centers in the U.S. The primary endpoint of this part is to determine the incidence rate of patients being alive and off mechanical ventilation at the end of day 28 with one of the key secondary endpoints being mortality. Assuming successful completion of this Phase 2 trial, Discovery plans to initiate a Phase 3 trial in 2003.

Surfactants are surface-active agents consisting of protein-lipid substances that are produced naturally in the lungs and are essential to the lungs' ability to absorb oxygen. They possess the ability to lower the surface tension of the fluid normally present within the air sacs in the lungs. In the absence of sufficient surfactant, these air sacs tend to collapse. As a result, the lungs do not absorb sufficient oxygen. Surfaxin, Discovery's engineered version of natural human lung surfactant, is intended to re-establish the lung's capacity to absorb oxygen. Surfaxin has been granted U.S. FDA Fast Track designation, and Orphan Drug designation by both the U.S. FDA and European Agency for the Evaluation of Medicinal Products.

About Discovery Laboratories

Discovery Laboratories, Inc. is a specialty pharmaceutical company leveraging its platform technology in humanized lung surfactants to develop novel respiratory therapies and pulmonary drug delivery products. The Company'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, the Company's lead product, is currently in two pivotal Phase 3 multinational 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 of the Company's humanized surfactant technology are being developed in an effort to treat other respiratory conditions such as asthma and as a novel pulmonary drug delivery vehicle to render drugs more effective when delivered to or via the respiratory tract. To serve the critical care marketplace, the Company is developing a dedicated sales and marketing capability through a collaboration with Quintiles Transnational Corp. for the United States, and has a strategic alliance with Laboratorios del Dr. Esteve S.A. for Europe and Latin America. Interested parties can receive corporate updates by sending their email addresses to dsc0@focuspartners.com. More information about Discovery Laboratories is available on the Company's Web site at www.discoverylabs.com.

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