



Surfaxin[®] (Lucinactant) Long-Term Survival Advantage vs. Comparators Published in *Pediatrics*

Surfaxin demonstrates statistically significant 1-year survival advantage vs. animal-derived surfactants Survanta[®] and Curosurf[®]

Warrington, PA — May 31, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announces publication of the one-year follow-up results from its SELECT and STAR Phase 3 clinical trials for Surfaxin[®], in *Pediatrics*, the premier medical journal for pediatric healthcare practitioners. The long-term data from the SELECT and STAR trials concluded that Surfaxin demonstrated a statistically significant survival advantage relative to existing animal-derived surfactants, Survanta[®] and Curosurf[®]. Surfaxin is pending approval and has received an Approvable Letter from the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants.

The article published in *Pediatrics* is entitled: One-Year Follow-up of Very Preterm Infants Who Received Lucinactant for Prevention of Respiratory Distress Syndrome: Results from 2 Multicenter Randomized, Controlled Trials (*Moya et al.*) *Pediatrics* Vol. 119 No. 6 June 2007.

Fernando Moya, M.D., Chair of the SELECT study Steering Committee and Director of Neonatology at the Coastal Area Health Education Center, North Carolina, commented, “The long-term outcomes from the pooled analysis are particularly important because they suggest that a next-generation surfactant therapy, such as Surfaxin, may save more babies’ lives while improving their chances for a healthy future. The prospective assessment of long-term outcomes from the SELECT and STAR trials is unique given direct comparisons between surfactant products. The data set from this recently published analysis sets a new bar for this category.”

Key Data Highlights:

- Treatment with Surfaxin significantly improved survival ($p=0.05$) through one-year of life compared with animal-derived surfactants, Survanta and Curosurf.
- Surfaxin significantly improved survival ($p=0.04$) through one-year of life when directly compared with Curosurf, the current market leader in Europe and current market growth driver in United States.
- Although treatment with Surfaxin improved survival in preterm children, no differences in neurologic outcomes through one-year of life were observed between treatment groups, however, Surfaxin demonstrated a statistically significant ($p\leq 0.05$) reduction in two important assessments of neurologic outcomes (reflex abnormality and gross tone) versus Survanta.

Robert J. Capetola, President and CEO of Discovery Labs, commented, “Publication of these data in *Pediatrics* represents an important validation of Surfaxin, the cornerstone of Discovery’s broad SRT pipeline. The neonatal medical community has repeatedly indicated a strong interest in long-term

outcomes assessment. No such assessment from the registration trials supporting use of currently prescribed animal-derived products has, to our knowledge, ever been conducted. Discovery is committed to provide this critically important information to the neonatal community. The article by Dr. Moya *et al.* supports a defined survival advantage for Surfaxin compared with current standard of care. We believe these long-term data will support significant differentiation for Surfaxin.”

About Surfaxin

Surfaxin is a precision-engineered version of natural human lung surfactant and contains Discovery Labs’ KL-4 peptide. Surfaxin, administered as a liquid-instillate, represents a potential alternative to the commercially available animal-derived surfactants. Data from Discovery Labs pivotal, multinational SELECT study demonstrate that Surfaxin is significantly more effective in the prevention of RDS and results in improved survival (continuing through at least one year of life) and other outcomes versus comparator surfactants. The SELECT and STAR (a supportive Phase 3 study) trials, as well as the pooled Phase 3 analysis, have been presented at several international medical meetings and the results from the two studies were published in *Pediatrics*. In addition, top-line results from Discovery Labs Phase 2 clinical trial for the prevention and treatment of BPD suggested that infants treated with up to five incremental standard doses of Surfaxin tended to have a lower incidence of death or BPD, a higher survival rate through 36 weeks post-menstrual age, and fewer days on mechanical ventilation.

About the medical journal, *Pediatrics*

Pediatrics, the official journal of the American Academy of Pediatrics, publishes papers on original research or observations and special feature articles in the field of pediatrics. *Pediatrics* serves as a medium for expression to the general medical profession as well as pediatricians. The Executive Board and Officers of the American Academy of Pediatrics select articles that appear in *Pediatrics*. The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adult. The Academy is committed to the attainment of optimal physical, mental, and social health for all infants, children, adolescents and young adults.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant. Discovery Labs believes that its proprietary SRT pipeline has the potential to advance respiratory medicine and address a variety of respiratory diseases affecting neonatal, pediatric and adult patients.

Discovery Labs lead product candidate, Surfaxin[®], is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants. Surfaxin is also being developed for other neonatal and pediatric indications. Aerosurf[™], Discovery Labs aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at www.Discoverylabs.com.

To the extent that statements in this press release are not strictly historical, 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 Labs actual results and could cause results to differ from those contained in these forward-looking statements are the risk that Discovery Labs may not profitably develop and market its products, the risk that financial market conditions may change, the risk that Discovery Labs will not be able to raise additional capital or enter into additional collaboration agreements, the risk that Discovery Labs will not be able to attract or retain qualified personnel or timely provide for a successful sales and marketing organization, risks relating to the progress of Discovery Labs research and development,, risks in the FDA or other regulatory agency review process generally, including that such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application or that approval by such regulatory agency may be withheld, delayed and/or limited by indications or other label limitations, risks that the Chemical, Manufacturing and Controls section of Discovery Labs New Drug Application will not satisfy the FDA, risks relating to the ability of Discovery Labs or Discovery Labs third party manufacturers and development partners to manufacture or provide Discovery Labs with adequate supplies of drug substances and expertise for completion of any of Discovery Labs clinical studies, risks related to the ability of Discovery Labs and its collaborators to develop, manufacture and successfully commercialize products that combine Discovery Labs drug products with innovative aerosolization technologies, risks relating to drug manufacturing by Discovery Labs, risks relating to the significant, time-consuming and costly research, development, pre-clinical studies, clinical testing and regulatory approval process for any products that Discovery Labs may develop independently or with Discovery Labs collaboration arrangements, risks relating to the development by other companies of competing therapies and/or technologies, risks relating to reimbursement and health care reform, and risks relating to securities, product liability and other litigation. 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 Labs 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.

Company Contact:

Lisa Caperelli, Investor Relations
215-488-9413