



Discovery Labs' Surfaxin[®](lucinactant) Phase 3 Results Published in *Pediatrics*, the Official Journal of the American Academy of Pediatrics

Warrington, PA — April 4, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announces publication of the results from its SELECT and STAR Phase 3 clinical trials for Surfaxin[®], in *Pediatrics*, a premier medical journal for pediatric healthcare practitioners. Published results from the SELECT and STAR trials concluded that Surfaxin provides potential advantages versus existing surfactant therapy and may be an effective therapeutic option for preterm infants at risk for Respiratory Distress Syndrome (RDS). Presentation of these data at multiple international medical congresses including the *Pediatric Academic Societies*, *European Society for Pediatric Research* and *Hot Topics in Neonatology*, and publication in a peer-reviewed journal such as *Pediatrics* validate these important studies.

Surfaxin is pending approval and has recently received an Approvable Letter from the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants.

Robert J. Capetola, President and CEO of Discovery commented, “We are extremely pleased that *Pediatrics* has published this data to make it available to the medical community. This publication, combined with our Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants, validates the potential for Surfaxin to increase survival and transform the treatment of respiratory disease in the Neonatal Intensive Care Unit (NICU).”

As previously reported, in the pivotal SELECT trial, Surfaxin significantly increased survival of premature babies with RDS compared with Exosurf[®], a non-protein containing synthetic surfactant, and Survanta[®], the leading animal-derived product prescribed in the United States. In addition, when treated with Surfaxin, more babies survived without developing debilitating chronic lung disease, also known as bronchopulmonary dysplasia (BPD), compared with those treated with Exosurf.

Surfactants are protein and lipid (fat) compositions that are produced naturally in the lungs and are essential for breathing. Presently, the FDA has approved surfactants as replacement therapy only for RDS in premature infants, a condition in which infants are born too soon and thus have an insufficient amount of their own natural surfactant. The FDA approved surfactants available today are either animal-derived or non-protein containing synthetic products. Animal-derived surfactants contain variable amounts of surfactant apoproteins, whereas the older-generation synthetic products contain only phospholipids and lack surfactant proteins which are necessary to optimize function.

Discovery's Surfaxin is a synthetic, peptide-containing, precision-engineered surfactant that contains sinapultide, a novel 21-amino acid peptide designed to mimic the function of the critical human surfactant protein, SP-B. Surfaxin is completely synthetic and thus avoids any potential risks associated with therapies derived from animal origin.

The articles selected for publication in *Pediatrics* are:

- A Multicenter, Randomized, Masked, Comparison Trial of Lucinactant, Colfosceril Palmitate, and Beractant for the Prevention of Respiratory Distress Syndrome Among Very Preterm Infants (*Moya et al.*) *Pediatrics* Vol. 115 No. 4 April 2005
- A Randomized, Controlled Trial of Lucinactant Versus Poractant Alfa Among Very Premature Infants at High Risk for Respiratory Distress Syndrome (*Sinha et al.*) *Pediatrics* Vol. 115 No. 4 April 2005

The pivotal SELECT trial was the largest, adjudicated, regulatory trial conducted in this therapeutic category's evolution. The SELECT trial was designed as a superiority trial to compare the efficacy and safety of Surfaxin with the non-protein containing synthetic surfactant, Exosurf and a bovine-derived surfactant, Survanta in the prevention of RDS and RDS-related deaths in premature infants. Based on the results, it was determined that Surfaxin is a significantly more effective surfactant preparation than Exosurf for the prevention of RDS and decreased RDS related mortality rates when compared with both comparators, Exosurf and Survanta. In the surviving population, Surfaxin also significantly reduced the incidence of BPD, compared with Exosurf.

“The data from the SELECT trial indicates that a new-generation surfactant replacement therapy such as Surfaxin will save more babies' lives while improving their chances for a healthy future, commented Fernando Moya, M.D., Chair of the SELECT study Steering Committee and Richard W. Mithoff Professor of Neonatal-Perinatal Medicine, Department of Pediatrics UT-Houston School of Medicine. “The successful conduct of this trial, which for the first time in this therapeutic class, included strict adjudication of all primary outcomes by an independent committee of leading neonatologists and pediatric radiologists, represents a new quality standard in surfactant clinical trials.”

The supportive, multinational STAR trial was designed as a non-inferiority trial comparing Surfaxin[®], to Curosurf, the porcine-derived surfactant which is the market leader in Europe. Curosurf is considered by many of the world's leading neonatologists to be the best surfactant currently approved. In the trial, Surfaxin was shown to be non-inferior to Curosurf and was well-tolerated.

Sunil Sinha, M.D., Ph.D., F.R.C.P, a leading European neonatologist and a Professor of Paediatrics at South Cleveland Hospital, United Kingdom, stated, “The results from the STAR trial are very exciting for the pediatric community. Surfaxin is a surfactant of the highest quality and is designed to overcome the potential limitations of animal-derived surfactants. The medical community will embrace a synthetic surfactant that can increase the odds for survival and reduce some of the long-term complications associated with prematurity such as BPD.”

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 adults. 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 biopharmaceutical company developing its proprietary surfactant technology as Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery's technology produces a precisely engineered surfactant that is designed to closely mimic the essential properties of natural 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 patients in the neonatal intensive care unit, critical care unit and other hospital settings, where there are few or no approved therapies available.

Discovery has received an Approvable Letter from the FDA for Surfaxin, the Company's lead product, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, and has filed a Marketing Authorization Application with the EMEA for clearance to market Surfaxin in Europe. Discovery is also conducting various clinical programs to address Acute Respiratory Distress Syndrome (ARDS) in adults, Bronchopulmonary Dysplasia (BPD) in premature infants, Neonatal Respiratory Disorders in premature infants, severe asthma in adults, and Meconium Aspiration Syndrome (MAS) in full-term infants.

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 Discovery's product development, events conditioned on stockholder or other approval, or otherwise as to future events, 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's actual results and could cause results to differ from those contained in these forward-looking statements are the risk that financial conditions may change, risks relating to the progress of Discovery's research and development, the risk that Discovery will not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for our aerosol and Surfactant Replacement Therapies), risk that Discovery will not be able to develop a successful sales and marketing organization in a timely manner, if at all, risk that Discovery's internal sales and marketing organization will not succeed in developing market awareness of Discovery's products, risk that Discovery's internal sales and marketing organization will not be able to attract or maintain qualified personnel, risk of delay in the FDA's or other health regulatory authorities' approval of any applications filed by Discovery, risks that any such regulatory authority will not approve the marketing and sale of a drug product even after acceptance of an application filed by Discovery for any such drug product, risks relating to the ability of Discovery's third party contract manufacturers to provide Discovery with adequate supplies of drug substance and drug products for completion of any of Discovery's clinical studies, other risks relating to the lack of adequate supplies of drug substance and drug product for completion of any of Discovery'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 Discovery's 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.

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