



Discovery Labs Surfaxin[®] Licensed In Italy by Dompé Farmaceutici

Warrington, PA — October 20, 2005 — Discovery Laboratories, Inc. (Nasdaq: DSCO) announced today that its development and marketing partner in Southern Europe, Laboratorios del Dr. Esteve, S.A. (Esteve) has sublicensed the distribution rights to Surfaxin[®] in Italy to Dompé Farmaceutici Spa (Dompé), a privately owned Italian company. Under this agreement Dompé will be responsible for sales, marketing and distribution in Italy of Surfaxin for the prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented, “Dompé is a long established and respected company with an important presence in the Italian pharmaceutical market and we are pleased about Esteve’s partnership with Dompé. The ability of a company like Dompé to make rapid decisions while offering strong sales and marketing capabilities will be a driver for Surfaxin to succeed in Italy.”

Dr. Manuel Sánchez Luna, Chief of the Neonatal Intensive Care Unit at Hospital General Gregorio Marañón (Madrid, Spain), commented, “Surfaxin potentially represents a significant advancement over the currently available surfactant products and could considerably impact the European neonatal community. It is not just another new surfactant but a new concept for the prevention and treatment of RDS in the newborn as well as bronchopulmonary dysplasia.”

Discovery has an alliance with Esteve for the development and marketing of Discovery’s broad portfolio of potential Surfactant Replacement Therapy (SRT) products, including Surfaxin, in Southern Europe, namely Spain, Italy, Portugal, Greece and Andorra. Under this alliance, Discovery is responsible for the manufacture and supply of all covered products and Esteve is responsible for all sales and marketing in their territory.

Discovery has received an approvable letter from the FDA for Surfaxin for the prevention of RDS in premature infants, and has filed a marketing authorization application with the EMEA for clearance to market Surfaxin in Europe.

Surfaxin is a precision-engineered, peptide-containing, synthetic surfactant that is designed to closely mimic the function of natural human lung surfactant and represents an innovative potential alternative for the animal-derived and non- protein containing synthetic surfactants. Surfactants are substances that are produced naturally in the lungs and are essential to the lungs’ ability to absorb oxygen and to maintain proper airflow through the respiratory system. Premature babies are born with a lack of natural surfactant in their lungs. Without surfactant, the air sacs in the lungs collapse and are unable to absorb sufficient oxygen resulting in RDS.

About Respiratory Distress Syndrome

RDS is a condition in which premature infants are born with an insufficient amount of their own natural surfactant. Premature infants born prior to 32 weeks gestation have not fully developed a natural lung surfactant and therefore need treatment to sustain life. This condition often results in the need for mechanical ventilation. RDS in premature infants affects approximately two million babies

worldwide with approximately 270,000 cases occurring in the developed world. Due to limitations associated with the currently approved animal-derived products, only approximately 150,000 infants are estimated to be receiving surfactant therapy worldwide.

About Dompé

Dompé is a leading European Pharmaceutical and Biotech Company, with an international presence through worldwide licensees and distributors network and sales of its proprietary products in more than 50 Countries. The Company has more than 850 employees, with consolidated sales of around 300 million euros.

About Esteve

Esteve is one of the largest pharmaceutical-chemical corporations in Southern Europe. Since 1960, Esteve has established strategic alliances with multinational pharmaceutical-chemical companies to market their products in Southern Europe. Esteve has established its own successful research and development capabilities, developing new chemical entities and manufacturing active pharmaceutical ingredients with its research products marketed in over 90 countries.

About Discovery Labs

Discovery Laboratories, Inc. is a biotechnology 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 precision-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 address respiratory diseases where there are few or no approved therapies available.

Discovery's SRT pipeline is initially focused on the most significant respiratory conditions prevalent in the neonatal intensive care unit. The Company's lead product, Surfaxin[®], for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA. Surfaxin is also being developed for the treatment of Chronic Lung Disease (CLD) in premature infants. Aerosurf[™], aerosolized SRT administered through nasal continuous positive airway pressure (nCPAP), is in development to address neonatal respiratory failures.

To address the various respiratory conditions affecting pediatric, young adult and adult patients in the critical care and other hospital settings, Discovery is conducting a Phase 2 clinical trial to address Acute Respiratory Distress Syndrome (ARDS) in adults, and is also developing aerosol formulations of SRT to address Acute Lung Injury (ALI), asthma, COPD, and other respiratory conditions.

For more information, please visit our corporate website 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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