DURECT Corporation Files IND for the Long Term Treatment of Asthma

CUPERTINO, Calif., Apr 2, 2002 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that it has filed an Investigational New Drug application to investigate the delivery of cromolyn sodium for the treatment of asthma. This IND was filed as part of an ongoing program to develop a product for the treatment of asthma and allergic rhinitis (seasonal allergies) utilizing one of the Company's proprietary biodegradable drug delivery platforms. Cromolyn sodium, a non-steroidal anti-allergy medication, is an FDA-approved drug for the management of mild-to-moderate persistent asthma and is recommended for early intervention and daily anti-inflammatory therapy. Cromolyn sodium has an excellent safety profile, and its position in asthma therapy is well-established.

Asthma is a serious, chronic, potentially life-threatening condition that affects approximately 15-17 million people in the U.S. Allergic rhinitis is the fifth most common chronic disease in the U.S., and affects as many as 40 million people in the U.S. Sales of asthma and allergic rhinitis treatments exceeded $5 billion in 2000.

Dr. Stephen Tilles, Executive Director of ASTHMA, Inc., Seattle, Washington, is the lead investigator for the initial trial. Dr. Tilles notes that, "cromolyn, a non-steroidal anti-allergy medication, has demonstrated itself to be one of the safest agents to control the onset of mild-to-moderate bronchospasm in asthma patients, without the detrimental side effects of commonly-used steroids. Cromolyn's traditional means of administration by inhalation causes difficulties with patient compliance, resulting in sub-optimal therapy and limited utility in asthma and seasonal allergies. DURECT's unique controlled-release drug delivery technology may provide the benefits of cromolyn to a much broader population of patients, particularly if it proves to be steroid-sparing. With optimal dosing, cromolyn may prove to be one of the most effective agents for the treatment of persistent asthma. Our staff looks forward to working with DURECT on this initial clinical trial."

Overall Study Design and Plan

The Phase I study will be a single-center study that will enroll patients with exercise-induced bronchospasm. Patients will be evaluated for five weeks. Efficacy will be assessed by evaluating pulmonary function and plasma concentrations of cromolyn sodium following an exercise challenge. Safety will be assessed by evaluating clinical laboratory tests, significant adverse events, physical examination and vital signs.

"Asthma and allergy are rapidly growing markets that are in need of a safe and effective therapeutic alternative with a longer duration of therapy," stated Jim Brown, CEO of DURECT. "The development of a biodegradable drug delivery product may have a significant impact on patient compliance, and we hope will expand the current therapeutic options for patient care."

DURECT Corporation (www.www.durect.com) is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the right amount at the right time. DURECT's lead product in development, the CHRONOGESIC(TM) (sufentanil) Pain Therapy System, a 3-month product for the treatment of chronic pain, completed a pilot phase III study in December 2001. DURECT owns three proprietary drug delivery platform technologies, including the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system).

NOTE: CHRONOGESIC(TM) is a trademark of DURECT Corporation. SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation.

The statements in this press release regarding DURECT's products in development, expected product benefits, product development plans, future clinical trials or potential product markets are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, DURECT's ability to research, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, finance its activities and operations, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 filed with the SEC on March 28, 2002, under the heading "Factors that may affect future results," and other periodic reports filed with the SEC. CHRONOGESIC is under development by DURECT and has not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

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