DURECT Initiates Pivotal Phase III Program for the CHRONOGESIC(TM) (Sufentanil) Pain Therapy System

CUPERTINO, Calif., Jul 9, 2002 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that it has begun dosing of patients in the first clinical trial of its pivotal Phase III program for the CHRONOGESIC(TM) (sufentanil) Pain Therapy System. The CHRONOGESIC product is a pain relief system that continuously delivers sufentanil systemically for three months and is intended for patients with opioid responsive malignant and non-malignant chronic pain. Sufentanil is a pain relief medication that is currently FDA-approved for use in hospitals as an analgesic. In previous clinical studies, the CHRONOGESIC product was shown to have a favorable safety and efficacy profile in over 70 patients.

“Our CHRONOGESIC therapy is the first systemic medication that may provide patients with uninterrupted pain treatment for three months from a single application. We believe the CHRONOGESIC therapy will be a significant improvement over currently available long-term pain therapies on the market today. We hope to provide physicians with a valuable medicine to potentially treat the millions of underserved patients suffering from chronic pain,” stated Jim Brown, President and Chief Executive Officer of DURECT. “We are very excited to bring this new pain therapy to this advanced stage of development. The initiation of our pivotal Phase III trials for this product represents an important milestone for DURECT.”

Pivotal Phase III program

The objective of the Phase III program is to demonstrate that patients can be safely transitioned from their existing pain relief medication to the CHRONOGESIC product without compromising their pain relief.

DURECT’s pivotal Phase III program is anticipated to consist of four clinical studies, which will enroll over 900 patients in total. The first trial is an open-label safety study evaluating the CHRONOGESIC product in at least 100 patients for a period of 12 months. The pivotal Phase III program will also include placebo-controlled safety and efficacy studies in the United States. DURECT also plans to conduct a study to compare the CHRONOGESIC product to an active control therapy to support European registration.

In the pivotal Phase III clinical trials, the primary endpoint is the success of CHRONOGESIC in replacing other opioids while maintaining or improving pain relief as indicated by an improvement in the pain visual analog score. Secondary endpoints will include quality-of-life improvements and improved gastrointestinal function such as constipation.

Previous Clinical Trials

In previous clinical trials for this product, DURECT developed a clinical strategy to permit transition from a variety of opioid medications to the

CHRONOGESIC product and demonstrated better pain control and patient preference for the CHRONOGESIC product. In September 2001, DURECT presented data from a Phase II trial that enrolled 66 patients experiencing chronic pain due to failed back surgery, cancer and other malignant and non-malignant causes. Patients were transitioned from their pre-study opioid medication to a six-week period of CHRONOGESIC therapy.

In a post-study survey, 60% of patients indicated a preference for CHRONOGESIC over their pre-study medication and 35% of patients preferred their previous medication (5% of patients indicated no preference). CHRONOGESIC also demonstrated improvements in select side effects when compared to pre-study medication.

The transition strategy developed in the Phase II trial was confirmed in an 18 patient pilot Phase III study, the results of which were presented in March 2002. In that trial patients were successfully converted from the Duragesic(R) product, a 3-day transdermal fentanyl patch, to the CHRONOGESIC product without observing clinically-relevant side effects or adverse events.

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 is a 3-month product for the treatment of chronic pain. 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).

The statements in this press release regarding DURECT's products in development, product development plans and clinical trials plans, 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, timely enroll patients and clinical sites in connection with its clinical studies, effectively administer its clinical trials, 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.

SOURCE DURECT Corporation

CONTACT:
Schond L. Greenway, Senior Director, Investor Relations and
Strategic Planning of DURECT Corporation, +1-408-777-1417 or
schond.greenway@durect.com

URL:
http://www.www.durect.com
http://www.prnewswire.com