DURECT Corporation Completes the Clinical Portion of Phase II Clinical Trial for DUROS Sufentanil

CUPERTINO, Calif., May 11 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today that the company has completed the clinical portion of its Phase II clinical trial for the company's lead product, DUROS sufentanil. The last patient visit was completed and data analysis and report writing are underway. Over 50 patients at 9 clinical centers completed the clinical portion of the study more than 3 months ahead of schedule. DUROS sufentanil is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is an FDA approved opioid that is currently used in hospitals as an anesthetic. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. DUROS sufentanil is intended for patients whose chronic pain is stable, opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain are in excess of $1 billion.

This Phase II trial was designed to determine the dose conversion from other approved opioid medications to DUROS sufentanil. DURECT utilized an advisory panel of leading clinical physicians and experts in the field of chronic pain to develop the protocol for the Phase II trial. The trial evaluated the safety and efficacy of continuous dose of sufentanil via a subcutaneously implanted DUROS sufentanil system in stable opioid responsive chronic pain patients. The information on relative potency and conversion charts collected in this study will be used in Phase III trials designed to demonstrate the safety and efficacy of the DUROS sufentanil product.

"We are very pleased at the progress that we have made with our Phase II trial for DUROS sufentanil. The accelerated pace exceeds our expectations," said James E. Brown, President and CEO of DURECT. "We believe that this reflects the potential benefits of this product to both patients and physicians. We believe DUROS sufentanil has the potential to be a more convenient, patient-friendly product that may provide an alternative to current therapies for the long term treatment of stable and opioid responsive chronic pain."

"We believe that the rapid patient enrollment and completion of this Phase II trial is due to the tremendous enthusiasm of our investigators for this product, which we expect to carry forward to our Phase III trials," said Dennis Fisher, MD, Vice President of Medical Affairs and Medical Director of DURECT.

DURECT Corporation is pioneering the development and commercialization of pharmaceutical systems to deliver the right drug to the right site in the right amount at the right time. DURECT's pharmaceutical systems combine technology innovations from the medical device and drug delivery industries with proprietary pharmaceutical and biotechnology drug formulations. These

capabilities can enable new drug therapies or optimize existing therapies based on a broad range of compounds, including small molecule pharmaceuticals as well as biotechnology molecules such as proteins, peptides and genes.

DURECT's second product in development, DUROS hydromorphone, continuously delivers hydromorphone to the spine. DURECT also sells FDA cleared catheters for the delivery of fluids to the inner ear and manufactures and sells and distributes the ALZET osmotic pump product for use in laboratory research.

Southern BioSystems, Inc., a wholly owned subsidiary of DURECT Corporation, researches, develops and manufactures controlled-release drug delivery products to help clients commercialize human and veterinary pharmaceuticals. Southern BioSystems has three drug-delivery platforms: the proprietary SABER(TM) delivery system, microspheres and drug-loaded implants. SABER(TM) is a biodegradable highly viscous liquid that can be formulated for oral, parenteral dermal or other routes of administration. Southern BioSystems has the capabilities to formulate microspheres for oral, parenteral dermal or other routes of administration. Southern BioSystems also develops drug-loaded implants and, through its subsidiary Birmingham Polymers, also manufactures biodegradable polymers.

Founded in 1998, DURECT is headquartered in Cupertino, CA. The company's World Wide Web site can be accessed at http://www.www.durect.com. The company's World Wide Web site for ALZET osmotic pumps, IntraEAR and Southern BioSystems, Inc. can be accessed at http://www.alzet.com, http://www.intraear.com and http://www.southernbiosystems.com, respectively. To join DURECT's email alert service, please register by selecting "Email Alerts" on the main Investor Relations web page at http://www.www.durect.com.

The statements in this press release regarding DURECT's products in development, product development plans, or expected product benefits, are forward-looking statements involving risks and uncertainties that could 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 develop, manufacture and commercialize its products, complete successful clinical trials, obtain product approvals from regulatory agencies, and build a manufacturing facility, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in the company's S-1 registration statement, filed with the SEC on September 22, 2000, 424(b) prospectus filed with the SEC on September 28, 2000, Quarterly Report on Form 10Q for the quarter ended September 30, 2000 filed with the SEC on November 14, 2000 and Annual Report on Form 10K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001.

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