DURECT Corporation Enrolls Patients in Phase II Clinical Trial for DUROS Sufentanil

CUPERTINO, Calif., Dec. 11 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced enrollment of the patients into a Phase II clinical trial for the company's lead product, DUROS sufentanil, for the treatment of chronic pain. DUROS sufentanil uses the DUROS osmotic delivery system to deliver sufentanil on a continuous basis for 3 months. Sufentanil is an off-patent, highly potent opioid that is currently used in hospitals as an anesthetic. Chronic pain, defined as pain lasting 6 months or longer, 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 and opioid responsive and results from a variety of malignant and non-malignant causes. Annual sales of opioids for the treatment of chronic pain are approximately $1 billion.

Traditionally, a Phase II clinical trial evaluates dose response concerns. In the case of DUROS sufentanil, because the drug has a well-understood safety and efficacy profile and the validity of the DUROS technology platform for providing drug therapy has been demonstrated by the Food and Drug Administration's approval of ALZA's Viadur product, the focus of this Phase II trial is designed to determine the dose conversion of 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, which is expected to include approximately 50 patients at 10-12 clinical centers, is projected to be completed in the second half of 2001. The trial is designed to address several issues relevant to the eventual commercial product. Patients with opioid-responsive pain will be converted from their present opioids (narcotics) to DUROS sufentanil with an equianalgesic dose identified in the crossover segment of the study. The trial will evaluate the safety and efficacy of continuous dose 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 to demonstrate the safety and efficacy of the DUROS sufentanil product.

Commenting on the trial, James E. Brown, D.V.M., President and Chief Executive Officer of DURECT, stated, "We are very pleased to reach this milestone for our lead product. We believe that DUROS sufentanil may have numerous advantages for the patient as well as the physician, including a consistent dosing regimen and increased patient compliance. 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."

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 initial portfolio of products combine the DUROS technology, a proven and patented drug delivery platform licensed for specified fields of use from ALZA Corporation, with drugs for which medical data on efficacy and safety are available. Founded in 1998, the Company is headquartered in Cupertino, CA. The Company's World Wide Web site can be accessed at http://www.www.durect.com. 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.

DUROS is a registered trademark of ALZA Corporation.

The statements in this press release regarding DURECT's products in development, product development plans, clinical trials, and 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, build a manufacturing facility, marketplace acceptance of DURECT's products and DURECT's ability to manage its growth and costs. 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, its 424(b) prospectus filed with the SEC on September 28, 2000 and its Quarterly Report on Form 10Q for the quarter ended September 30, 2000 filed with the SEC on November 13, 2000.

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