DURECT Corporation Announces Completion of Patient Enrollment in Phase II Clinical Trial for DUROS Sufentanil

CUPERTINO, Calif., March 9 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today that the company has completed patient enrollment of its Phase II clinical trial for the company's lead product, DUROS sufentanil. Over 50 patients at 10 clinical centers were enrolled in the trial more than one-quarter ahead of schedule. DURECT anticipates meeting with the FDA by early fall 2001 for its end of Phase II meeting for this product. DUROS sufentanil is designed to deliver sufentanil on a continuous basis for 3 months for the treatment of chronic pain. Sufentanil is a 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 is 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 will evaluate 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 to demonstrate the safety and efficacy of the DUROS sufentanil product.

As a result of the acceleration of the Phase II clinical studies, DURECT expects to begin additional development activities, including pharmacokinetic and bioavailability studies for DUROS sufentanil, which were originally planned for the second half of 2001. DURECT expects to incur additional expenditures of approximately $500,000 to $750,000 associated with these activities in the second quarter of 2001.

"We are very pleased at the progress that we have made with patient enrollment for 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."

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.

In addition to DUROS sufentanil, DURECT's second product in development, DUROS hydromorphone, is a DUROS-based pharmaceutical system for the delivery of hydromorphone to the spine for the treatment of end-stage cancer pain. DURECT is also selling FDA cleared catheters for the delivery of fluids to the inner ear. DURECT also manufactures, sells and distributes the ALZET(R) osmotic pump product for use in laboratory research.

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. 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, manage its growth and costs, 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 and 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 14, 2000.

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