DURECT Announces Chronogesic Preliminary Clinical Results of Phase II Trial

CUPERTINO, Calif., June 29 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced today the preliminary results of its Phase II clinical trial for its lead product, a 3-month continuous infusion subcutaneous implant for the treatment of chronic pain. The product, previously referred to as DUROS sufentanil, has been given the product name Chronogesic(TM). The preliminary results of the Phase II study are being presented to leading pain clinicians from around the world at the 2nd World Congress of the World Institute of Pain held June 27-30, in Istanbul, Turkey.

Preliminary results from the Phase II study showed that patients had clinically significant improvement in pain control and had reductions in some opioid side effects when treated with Chronogesic compared to the patients' previous opioid therapies. A full analysis of the Phase II data is currently underway and the complete findings will be available upon completion of Phase II study analysis.

This Phase II clinical trial was designed to determine the dose conversion strategy from other approved opioid medications to Chronogesic, and to evaluate the safety and efficacy of the Chronogesic therapy. The study enrolled adults ranging in age from 26 to 68 at 9 clinical sites. The study included patients whose chronic pain is stable and opioid responsive (daily opioid requirements of 100-1,000 mg of oral morphine equivalents) and results from a variety of malignant and non-malignant causes. The blinded randomized crossover portion of the study was designed to address conversion from other opioids to Chronogesic, followed by an open-label portion where Chronogesic was implanted in patients for up to 6 weeks, and safety and efficacy assessed.

"We believe Chronogesic, which is designed to provide 3 months of continuous relief for chronic pain patients, represents a significant advancement in pain therapy and adds a valuable tool to the treatment options for chronic pain patients," stated Dr. Dennis Fisher, Vice President of Medical Affairs and Medical Director of DURECT. "The preliminary outcomes from this study are consistent with the positive reaction of physicians about our product, as demonstrated by completion of patient enrollment for this study in less than three months and three months ahead of schedule. Most of the physicians from our Phase II trial and numerous investigators from around the world have expressed strong interest in participating in our upcoming Phase III trials."

"These preliminary results support our belief that Chronogesic 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," stated James E. Brown, CEO 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.

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://wsww.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 results, 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, successfully complete clinical trials, obtain product and manufacturing approvals from regulatory agencies, and validate and qualify 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 March 31, 2001 filed with the SEC on May 11, 2001 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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