DURECT Corporation Reports Initiation of Phase III Program for Chronogesic(TM

CUPERTINO, Calif., Nov. 1 /PRNewswire/ —
DURECT Corporation (Nasdaq: DRRX) announced during its third quarter financial results conference call yesterday that the company has commenced its Phase III program for Chronogesic(TM), for the treatment of chronic pain. The primary objectives of the Phase III program are to continue to demonstrate that the product is safe, that patients can be transitioned from use of a variety of existing opioids such as pills and patches to use of Chronogesic(TM) and that the product is effective and provides pain relief at least equivalent to the patient's existing pain therapy.

The focus of the recently completed Phase II trial was to determine the relative potency of fentanyl, the active agent in Duragesic(R) as compared to sufentanil, the active agent in Chronogesic(TM). This trial determined that sufentanil was 7.5 times more potent than fentanyl. In order to convert patients from their existing opioid to Chronogesic(TM), DURECT plans to leverage the extensive experience already available on how to transition patients from use of a variety of opioids to Duragesic(R). The initial focus of DURECT's Phase III clinical development efforts is to confirm the method developed from the Phase II trial to transition patients from Duragesic(R) to Chronogesic(TM).

In keeping with this initial focus, DURECT announced that it has completed the clinical portion of a pilot Phase III study to evaluate the procedures necessary to safely transition patients from Duragesic(R) to Chronogesic(TM). Data analysis from this trial is ongoing, and a preliminary report of the results is expected early in 2002.

"We are excited to report that we have started our Phase III program and we continue to aggressively make progress towards initiation of pivotal Phase III clinical trials," stated James Brown, CEO of DURECT. "During the Phase II trial for Chronogesic(TM), patients reported that Chronogesic(TM) provided better pain control and fewer side effects, resulting in a strong preference by patients for Chronogesic(TM) versus other medicines used prior to the study. We believe that Chronogesic(TM) offers patients a better quality-of-life alternative to currently available therapies for the long-term treatment of stable and opioid responsive chronic pain."

There will be an audio archive available of DURECT's Third Quarter 2001 Earnings Conference Call on DURECT's website at http://www.www.durect.com under the Audio Archive section of "Investor Relations."

DURECT Corporation 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 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 focuses on the treatment of chronic diseases including pain, CNS disorders, cardiovascular disease and cancer. DURECT holds an exclusive license from ALZA Corporation to develop and commercialize products in selected fields based on the DUROS(R) implant technology. Chronogesic(TM), a 3-month continuous infusion subcutaneous implant for the treatment of chronic pain, is the first product in this series and completed phase II testing in June 2001. DURECT also owns three proprietary erodible implant platform technologies, including SABER(TM) (a patented and versatile depot injectable useful for protein delivery), microspheres and drug-loaded implants. DURECT also commercializes IntraEAR(R) catheters, which have been used by physicians to treat inner ear disorders.

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 .

NOTE: Chronogesic(TM), SABER(TM) and IntraEAR(R) are trademarks of DURECT Corporation. DUROS(R) is a trademark of ALZA Corporation. Duragesic(R) is a registered trademark of Janssen Pharmaceutica Products, L.P.

The statements in this press release regarding DURECT's clinical trials, anticipated results, products in development, expected product benefits, product development plans or potential product markets 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 successfully complete clinical trials, research, develop, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, validate and qualify a manufacturing facility and manage its growth and expenses, as well as marketplace acceptance of DURECT's products. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001 filed with the SEC on August 14, 2001, and Annual Report on Form 10-K for the fiscal year ended December 31, 2000 filed with the SEC on March 30, 2001, under the heading "Factors that may affect future results."

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