# DURECT Announces Positive Preliminary Results from Transdermal Sufentanil Patch Study in Patients

CUPERTINO, Calif., Dec 26, 2005 /PRNewswire via COMTEX News Network/ — CUPERTINO, Calif., Dec. 26 /PRNewswire-FirstCall/–DURECT Corporation
(Nasdaq: DRRX), an emerging specialty pharmaceuticals company, announced today positive preliminary results from a multiple dose clinical study in chronic pain patients for DURECT's TRANSDUR(TM)-based sufentanil patch.

(Logo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO )

"The preliminary results of this Phase II clinical study for the TRANSDUR-Sufentanil patch indicate that the product performed as designed. The top-line preliminary results of this study showed that patients can be converted from the Duragesic(R) product to the TRANSDUR-Sufentanil product safely without observing clinically relevant severe adverse events. Dosing on TRANSDUR-Sufentanil was repeated for up to 4 consecutive weeks," said James E. Brown, DURECT's President and CEO.

Clinical Study Design (Phase II)

The clinical study was an open-label study that was designed to evaluate the transition of patients from Duragesic (commercial fentanyl patch) to the TRANSDUR-Sufentanil patch. The clinical study also evaluated the pharmacokinetics and safety of repetitive applications of the sufentanil patch in chronic pain patients for a period of up to four weeks. The clinical trial was conducted at 2 clinical sites (one in the United States and the other in Europe) and enrolled 13 adult patients in the primary study with malignant or non-malignant chronic pain.

Preliminary data indicate that all primary endpoints for the study were achieved, which include:

— Pharmacokinetic — Evaluation of plasma level data indicate that TRANSDUR-Sufentanil performed as designed by achieving its target delivery profile of providing a rapid onset of drug and a delivery duration of over 7 days. Targeted plasma levels over the consecutive 4-week period (repetitive applications of TRANSDUR-Sufentanil) were achieved as intended.

— Safety — The product was tolerated well with no apparent safety issues over the 4-week treatment period.

Preliminary Efficacy Observations:

— As this was an open label study, conclusions on efficacy cannot be drawn; on average, pain levels remained stable after the transition to TRANSDUR-Sufentanil.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. Additional information about DURECT is available at www.www.durect.com.

On March 14, 2005, DURECT granted Endo Pharmaceuticals Inc. the exclusive license to develop and commercialize the TRANSDUR-Sufentanil patch in the U.S. and Canada. This study was initiated prior to DURECT licensing this product to Endo.

DURECT Forward-Looking Statement

The statements in this press release regarding DURECT's and its collaborative partners' products in development, anticipated product benefits, and clinical trial results and plans are forward-looking statements involving risks and uncertainties that can 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 (and that of its third-party collaborators', where applicable) abilities to successfully enroll and complete clinical trials, complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize the product candidate, as well as marketplace acceptance of the product candidate. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005 filed with the SEC on October 13, 2005 under the heading "Factors that may affect future results."



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