DURECT Initiates Phase II Program for Its Sufentanil Patch Product

CUPERTINO, Calif., Feb. 16 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceuticals systems company, today announced the initiation of the Phase II program for DURECT's TRANSDUR(TM)-based sufentanil patch. Based on the results of our Phase I trial for our TRANSDUR-Sufentanil patch that showed good safety, tolerability and drug release for up to 7 days, we initiated the first clinical trial in our Phase II program.

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"The initiation of the Phase II program for the TRANSDUR-Sufentanil patch is an important milestone for us. We have been able to move this program rapidly from Phase I in October 2004, in part due to our Phase II and dose conversion data from our clinical studies with our CHRONOGESIC(R) product," said James E. Brown, DURECT's President and CEO. "Our previous experience with the systemic delivery of sufentanil in approximately 100 patients with CHRONOGESIC is directly applicable to the development of our TRANSDUR-Sufentanil patch."

Phase II Program

The objectives of the Phase II program are to evaluate the pharmacokinetics, efficacy, and safety of repetitive applications of our sufentanil patch in chronic pain patients for a period of up to four weeks.

About TRANSDUR-Sufentanil

DURECT's TRANSDUR-based transdermal sufentanil product is intended to provide extended chronic pain relief for up to seven days, as compared to the three days of relief provided with currently available opioid patches. Further, we anticipate that the small size of our sufentanil patch (potentially as small as 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) may offer improved convenience for patients. Worldwide sales for DURAGESIC(R), a leading transdermal fentanyl product, exceeded $2.1 billion in 2004.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceuticals systems 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. These platform technologies include the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the ORADUR(TM) sustained release oral gel-cap technology (an oral sustained release technology with several potential abuse deterrent properties), the DURIN(TM) Biodegradable Implant (drug-loaded implant system), the TRANSDUR(TM) transdermal technology and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also partners with pharmaceutical

companies to develop and commercialize proprietary and enhanced pharmaceutical products based on its technologies. DURECT has five disclosed on-going development programs of which three are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

The statements in this press release regarding DURECT's products in development and product development 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 ability to complete the design, development, and manufacturing process development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, manage relationships with third parties, finance its activities and operations, as well as marketplace acceptance of these products. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 filed with the SEC on November 5, 2004 under the heading "Factors that may affect future results."

SOURCE DURECT Corporation

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