DURECT Completes Dosing of the Phase I Pharmacokinetic Study for Its Sufentanil Patch Product and of the First Cohort of the Phase II Study for Its Post-Operative Pain Relief Depot

CUPERTINO, Calif., Feb. 10 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceuticals systems company, today announced the completion of dosing of the Phase I pharmacokinetic study for DURECT's TRANSDUR(TM)-based sufentanil patch. The Company also announced the completion of dosing of the first cohort of the on-going Phase II clinical study for DURECT's SABER(TM)-based post-operative pain relief depot product and is actively enrolling patients in the second cohort.

"Today, we are pleased to announce the completion of dosing of the Phase I pharmacokinetic study for our TRANSDUR sufentanil patch. Our announced goal for this program was to complete this study in the first half of 2005," said James E. Brown, DVM, DURECT's President and Chief Executive Officer. "In addition, the completion of dosing of the first cohort for our on-going Phase II trial for our SABER-Bupivacaine product candidate is an important milestone and advances this product to the next step in the clinical program. We believe that these products, once approved, will provide a significant improvement over currently available pain management therapies on the market today."

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.

DURECT's SABER-based post-operative pain relief depot product candidate is intended to be administered around a surgical site after surgery to provide up to 72 hours of regional pain relief and is based on our patented SABER delivery system. We believe this product could potentially reduce hospital stays and the amount of traditional post-surgical pain medications needed by patients, as well as the side effects that result from the use of concomitant opioid medications. We believe that there are currently more than 25 million surgical procedures performed annually in the US for which this product could be potentially used.

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.

NOTE: SABER(TM), ORADUR(TM), DURIN(TM), TRANSDUR(TM) and MICRODUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners.

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 10Q 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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