DURECT Initiates Phase I Trial for Its Proprietary Transdermal Sufentanil Patch

Patch to be Highlighted at ASA 2004 Annual Meeting

CUPERTINO, Calif., Oct. 22 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) today announced the initiation of a phase I clinical trial for a new proprietary transdermal sufentanil product. The trial consists of a pharmacokinetic study in normal, healthy volunteers in Europe. The objectives of the clinical study are to determine the safety and tolerability of DURECT's transdermal sufentanil patch as well as evaluate the pharmacokinetics of sufentanil following transdermal administration. Sufentanil is a pain relief medication that is currently FDA-approved for use in hospitals as an analgesic and is the active ingredient in DURECT's CHRONOGESIC(R) product under development. DURECT's 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 patches. Further, DURECT anticipates that the small size of the DURECT sufentanil patch (approximately 1/5th the size of current 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 $1.6 billion in 2003.

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

Transdermal Sufentanil Patch Product Description

DURECT's sufentanil transdermal patch product potentially offers the following benefits over current transdermal fentanyl patches:

- Increased duration of pain relief for up to seven days
- Smaller patch size (approximately 1/5th the size of current transdermal fentanyl patches for a therapeutically equivalent dose)
- We anticipate that other potential benefits could be:
- Improved convenience and patient compliance
- Reduced skin irritation
- Cosmetic and quality of life improvements
- Improved patch adhesion
- Easier for high dose patients who require multiple transdermal patches

"In our Phase II study for our CHRONOGESIC product, where sufentanil is the active ingredient, the data showed 2-to-1 patient preference for the therapy, better pain control and an improved side effect profile when compared to other opioid medications on the market. We anticipate that some of these benefits will also be applicable to our transdermal sufentanil product," stated James E. Brown, DVM, President and CEO of DURECT. "We are leveraging the knowledge and infrastructure relating to sufentanil gained from our considerable work with this compound to the development of our transdermal product. We believe that our transdermal product will be additive and complementary to DURECT's other pain-related products currently under

development.”

American Society of Anesthesiologists (ASA) 2004 Annual Meeting Presentation

Pamela Palmer, M.D., Ph.D., Professor, Department of Anesthesiology and Peri-Operative Care, and Medical Director of the Pain Management Center at University of California, San Francisco (UCSF), will be delivering a presentation discussing several innovative approaches to pain management at this weekend’s ASA meeting in Las Vegas, Nevada. The presentation, entitled “Pharmacologic Approaches to Pain Management,” will highlight details of DURECT’s transdermal sufentanil patch and will be made on Saturday, October 23, 2004 at 8:30 a.m. in rooms N115-116 at the Las Vegas Convention Center.

About DURECT Corporation

DURECT Corporation is a 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. 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 DURING(TM) Biodegradable Implant (drug-loaded implant system) 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), MICRODUR(TM) and CHRONOGESIC(R) 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, product development plans, anticipated clinical trials and potential markets 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 these products, manufacture and commercialize these products, obtain product and manufacturing approvals from regulatory agencies as well as marketplace acceptance of these products. Further information regarding these and other risks is included in DURECT’s Annual Report on Form 10-K for the fiscal year ended December 31, 2003 filed with the SEC on March 11, 2004, DURECT’s Quarterly Report on Form 10-Q and other periodic reports filed with the SEC under the heading “Factors that may affect future results.”

The transdermal sufentanil patch and CHRONOGESIC(R) products referred to in this press release are under development and have not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

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