

# ORADUR(TM) Technology Milestone: Remoxy(TM) (ORADUR-Based Oxycodone) Commences Pivotal Phase III Program

CUPERTINO, Calif., May 5 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) reported today that a pivotal Phase III program has been initiated for Remoxy(TM), an abuse-resistant pain medicine under development based on DURECT's patented ORADUR(TM) technology incorporating the opioid oxycodone. The event was announced on May 4 by Pain Therapeutics, Inc. (Nasdaq: PTIE), DURECT's licensee of the rights to Remoxy and other ORADUR-based products incorporating oxycodone and three other opioid compounds. According to Pain Therapeutics, the Remoxy pivotal Phase III program benefits from a Special Protocol Assessment from the FDA and about 20 clinical sites across the U.S. are now initiated for the Remoxy study.

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

"We are very pleased with development progress of Remoxy, and if approved, look forward to its commercialization by King Pharmaceuticals, Inc. We are also delighted with the continued advancement of our ORADUR technology platform," said James E. Brown, D.V.M., President and CEO of DURECT. "Our ORADUR platform has the potential to be the basis of numerous other innovative products given its unique combination of sustained-release and abuse-resistant properties. We look forward to developing additional sustained release oral gel-cap products containing active agents prone to abuse."

#### **About ORADUR**

ORADUR sustained released oral gel-cap technology provides the unique characteristics of Remoxy and the referenced follow-on products. Products based on the ORADUR technology can take the form of an easy to swallow gelatin capsule that uses a high-viscosity base component, SABER(TM), to provide sustained release of active ingredients for a period of from 12 to 24 hours of drug delivery. Oral dosage forms based on the ORADUR gel-cap may also have the added benefit of being less prone to abuse than other controlled release dosage forms on the market today. ORADUR-based products can be manufactured by a simple process using conventional methods making them readily scalable. These properties have the potential to make ORADUR-based products an attractive option for pharmaceutical companies that seek to develop tamper and abuse resistant oral products.

### **About Remoxy**

Remoxy is an oral, long-acting oxycodone capsule under development by Pain Therapeutics, Inc. and King Pharmaceuticals, Inc. that incorporates several abuse-deterrent properties and offers the convenience of twice-a-day dosing. Remoxy is formulated with DURECT Corporation's ORADUR technology under a development and license agreement between DURECT and Pain Therapeutics. Under the terms of the license agreement between Pain Therapeutics and DURECT, Pain Therapeutics has exclusive worldwide rights to develop and to commercialize



Remoxy and other ORADUR-based products using oxycodone and three other opioid drugs. DURECT is reimbursed for formulation and other work performed under its agreement with Pain Therapeutics, and will receive milestone payments based on the achievement of certain technical, clinical or regulatory milestones, in addition to receiving royalties on end product sales. Pain Therapeutics has sublicensed the commercialization rights of Remoxy to King Pharmaceuticals. Oxycodone is the active drug ingredient in Remoxy and in the branded product OxyContin(R). OxyContin(R), the leading brand name opioid used in the treatment of moderate-to-severe pain, has U.S. sales of \$1.9 billion for the year ended December 2004. Drug abusers can easily extract oxycodone from OxyContin(R) tablets in order to induce a quick and powerful euphoric high. Oxycodone abusers risk respiratory depression, which can be fatal, and opioid addiction.

## About DURECT

DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies. The company is developing pharmaceutical systems to deliver the right drug to the right place in the right amount at the right time to treat chronic and episodic diseases and conditions.

Forward Looking Statement

### **DURECT Forward-Looking Statement**

The statements in this press release regarding DURECT's and our collaborators' investigational products, development and clinical trial plans, commercial potential and possible economic returns 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' abilities to successfully design, enroll, conduct 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 Annual Report on Form 10-K for the year ended December 31, 2005 filed with the SEC on March 16, 2006 under the heading "Risk Factors."

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

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