

# DURECT Highlights Major Commercial Strategic Alliance for ORADUR(TM) Sustained Release Oral Gel-cap Technology

CUPERTINO, Calif., Nov. 11 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced the validation of the commercial potential of its ORADUR(TM) sustained release oral gel-cap technology with the recently announced strategic alliance to develop and commercialize Remoxy(TM), an ORADUR-based novel long-acting, abuse-deterrent oral formulation of oxycodone and other ORADUR-based products candidates using three other opioid drugs. On November 10, 2005, King Pharmaceuticals, Inc. and Pain Therapeutics, Inc. announced that the companies have entered into a strategic alliance to develop and commercialize Remoxy and other ORADUR-based abuse-deterrent products using three other opioid drugs.

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

"We are very pleased to have King Pharmaceuticals endorse the commercial potential for products based on our ORADUR platform technology. We are excited to have a strong commercial organization such as King Pharmaceuticals responsible for the commercialization of these products. This collaboration is just one example of pharmaceutical companies looking for unique products based on novel, patented technology platforms such as ours to address large and growing unmet medical needs," stated James E. Brown, DVM, President and Chief Executive Officer.

"We look forward to working with King and Pain Therapeutics to bring Remoxy and these other long-acting opioid drugs to the marketplace and generating significant value from these products for our shareholders. Furthermore, we look forward to developing additional innovative sustained release oral gel-cap products that utilize other opioids and other active agents prone to abuse."

"King is highly committed to making Remoxy and the three follow-on ORADUR-opioid products a commercial success. We believe that this represents a great market opportunity based upon the unmet medical need for narcotics with reduced abuse potential," stated Brian Markison, President and Chief Executive Officer of King Pharmaceuticals, Inc.

### 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 controlled 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. 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 joint development and license agreement. 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 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. Oxycodone is also the active drug ingredient in OxyContin(R), the leading brand name opioid used in the treatment of moderate-to-severe pain, with U.S. sales of nearly \$2 billion for the 12-months ending August 2005, according to IMS Health data. Oxycodone is also the active drug ingredient in Remoxy and in the branded product OxyContin(R). 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.

# Remoxy - Phase III Clinical Program

Pain Therapeutics is currently designing a pivotal Phase III study with Remoxy in patients with severe chronic pain. According to Pain Therapeutics, the trial is expected to begin in January 2006.

### **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. 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 collaborates 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 four 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.

## **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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