



# DURECT Announces Positive Clinical Results With Its ORADUR(TM) Sustained Release Oral Gel-Cap Technology

CUPERTINO, Calif., July 6 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced the advancement of its ORADUR(TM) sustained release oral gel-cap technology (formerly referred to as the SABER(TM) oral gel-cap technology) with positive human clinical results for Remoxy(TM). Remoxy is a novel long-acting oral formulation of oxycodone based on DURECT's ORADUR technology under development by Pain Therapeutics, Inc., which is targeted to decrease the potential for drug misuse or abuse. On June 29, 2004, Pain Therapeutics announced the results of studies conducted in human volunteers in the United Kingdom to confirm Remoxy's anti-abuse properties and to assess the drug's pharmacokinetics.

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

"We are very pleased with the progress that Pain Therapeutics has made thus far with the clinical study results for Remoxy(TM). These results reinforce our belief that products developed with our ORADUR sustained release oral gel-cap technology may offer a variety of benefits, including the potential to reduce abuse when compared to current long-acting dosage forms that are on the market today," stated James E. Brown, DVM, President and CEO of DURECT. "We look forward to working with a variety of pharmaceutical companies, including Pain Therapeutics, to develop more innovative sustained release oral gel-cap products using this exciting technology."

## About ORADUR

The results of the Remoxy clinical studies reported were attributed to the unique characteristics of the ORADUR sustained released oral gel-cap technology. Products based on the ORADUR technology can take the form of an easy to swallow gelatin capsule that uses a high-viscosity base component, such as sucrose acetate isobutyrate (SAIB), 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. ORADUR is a patented technology based on sucrose acetate isobutyrate, a high-viscosity, biodegradable liquid matrix that forms the



basis for a number of different injectable depot and oral gel-cap drug candidates, including Remoxy. 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 certain other opioid drugs formulated with DURECT's ORADUR technology. 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 product sales.

#### About DURECT Corporation

DURECT Corporation ([www.durect.com](http://www.durect.com)) is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the right amount at the right time. DURECT's lead product in development is CHRONOGESIC(R), a 3-month product for the treatment of chronic pain. DURECT also owns a number of proprietary drug delivery platform technologies, including 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 (oral drug delivery technology), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system) upon which DURECT is developing a pipeline of other products.

NOTE: CHRONOGESIC(R), SABER(TM), ORADUR(TM), MICRODUR(TM) and DURIN(TM) are trademarks of DURECT Corporation. Remoxy(TM) is a trademark of Pain Therapeutics, Inc. All other trademarks referred to belong to their respective owners.

The statements in this press release regarding DURECT's and Pain Therapeutics' 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 and Pain Therapeutics' abilities 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 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 10Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

CHRONOGESIC and other products mentioned above are under development and have not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

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