DURECT Corporation Announces Initiation of Phase III Studies for Remoxy, a Novel Oral Pain Medication using the ORADUR(TM) Gel-Cap

CUPERTINO, Calif., Dec. 23 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceutical systems company, announced today the initiation of Phase III clinical testing for Remoxy(TM), a novel long-acting, abuse-deterrent oral formulation of oxycodone based on DURECT's ORADUR(TM) technology licensed to Pain Therapeutics, Inc. 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. On December 6, 2004, in a subsequent study, Pain Therapeutics announced the results of a head-to-head comparison of the abusability of Remoxy versus Oxycontin(R), a brand name narcotic painkiller with annual sales exceeding $1.9 billion.

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

"This represents a significant milestone for our ORADUR franchise and we are very pleased with the rapid progress by which this partnered program has advanced into late stage clinical development. Thus far, these clinical 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. "Beyond our partner Pain Therapeutics, we have ongoing feasibility activities utilizing our ORADUR and look forward to expanding our relationships with a number of pharmaceutical companies to develop additional innovative sustained release oral gel-cap products that utilize select opioids and other potentially abused active agents."

The positive results of the Remoxy clinical studies reported to date 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, SABER(TM) or 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. Oxycodone is also the active drug ingredient in OxyContin, a brand name narcotic painkiller with annual sales exceeding $1.9 billion. 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 injectible 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 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) 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.

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."
Remoxy(TM) 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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