DURECT Corporation Announces Positive Phase III Clinical Results for Remoxy, a Novel Oral Pain Medication using the ORADUR(TM) Gel-Cap

CUPERTINO, Calif., Sept. 9 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX), an emerging specialty pharmaceutical company, announced today that Pain Therapeutics, Inc. has achieved positive Phase III clinical results for Remoxy(TM), a novel long-acting, abuse-deterrent oral formulation of oxycodone based on DURECT's ORADUR(TM) technology being developed under license from DURECT.

"These results represent 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. "We continue working 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."

Phase III Study Design and Results

The randomized, double-blinded study was designed to compare the safety and efficacy of Remoxy against placebo in osteoarthritic patients with moderate-to-severe chronic pain. Over 209 patients were enrolled in over 20 U.S. clinical sites. Patients were treated with Remoxy 20 mg or matching placebo twice daily over a 4-week study period. The results announced by Pain Therapeutics demonstrated a statistically significant percent decrease in pain scores for patients using Remoxy as compared to placebo, as measured by a standard Likert Pain Scale. Patients also reported a statistically significant difference in quality of life using Remoxy as compared to placebo, as measured by as measured by a standard SF-12 Health Survey and in patients' self-reported Quality of Analgesia. No drug-related safety issues were noted in the study, and as expected opioid-related adverse events (including nausea/vomiting, dizziness, pruritis (itching) and somnolence/sedation) and drop-out rates were higher in the Remoxy arm compared to placebo. Pain Therapeutics intends to initiate a second Phase III registration study by year-end 2005.

Remoxy draws upon 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 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 http://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 products in development, anticipated product benefits and clinical trial 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 ability to complete the design, development, and manufacturing process development of the product candidate and obtain approvals from regulatory agencies to manufacture the product candidate, as well as Pain

Therapeutics' ability to initiate, enroll and complete clinical trials and obtain product approvals from regulatory agencies to commercialize the product candidate, and 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 June 30, 2005 filed with the SEC on August 4, 2005 under the heading "Factors that may affect future results."

SOURCE DURECT Corporation

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