New Drug Application Submitted for Remoxy(TM) (ORADUR(TM)-Based Oxycodone)

CUPERTINO, Calif., June 10 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today that a New Drug Application (NDA) for Remoxy(TM) (ORADUR(TM)-based oxycodone) has been submitted to the U.S. Food and Drug Administration (FDA). Remoxy, an investigational drug, is a long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT's ORADUR technology, Remoxy is designed to resist common methods of prescription drug misuse and abuse.

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

"We are pleased that the first NDA has been filed for a drug candidate using one of DURECT's platform technologies," stated James E. Brown, DVM, President and CEO of DURECT. "The abuse of pain medications is a widespread problem in this country and addressing that issue is clearly in the public interest. We designed our ORADUR technology to enable the abuse resistant properties of drug candidates such as Remoxy which has the potential to be the first oxycodone on the market that deters common methods of abuse."

Remoxy is being developed by Pain Therapeutics under license from DURECT, and Pain Therapeutics has, in turn, sublicensed the commercialization rights to the drug candidate to King Pharmaceuticals. King and Pain Therapeutics have stated that they believe the NDA for Remoxy benefits from years of rigorous and independent scientific and clinical testing, and the NDA includes animal and human data from extractability, pharmacokinetic, toxicology and clinical studies.

About the NDA for Remoxy (as announced by King and Pain Therapeutics)

Pain Therapeutics submitted the NDA in accordance with the FDA's Electronic Common Technical Document specifications. Pursuant to Prescription Drug User Fee Act (PDUFA) guidelines, the FDA is expected to determine whether to accept the NDA for filing within 90 days. At that time Pain Therapeutics will also learn if the NDA filing was granted priority review. A Priority Review designation is given to drugs that offer real advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a NDA is reduced from 12 months to approximately 6 months.

About the Development Program for Remoxy (as announced by King and Pain Therapeutics)

The development program for Remoxy consisted of several clinical studies, including one pivotal Phase III study conducted under a Special Protocol Assessment (SPA), which evaluated the safety and efficacy of Remoxy in over 400 patients with osteoarthritis. With a SPA, the study design, endpoints and statistical analyses needed to support approval were agreed upon by the FDA prior to initiating the study and are considered binding. Pain Therapeutics and King have stated that they believe that the SPA for Remoxy remains in full-force without modification. The following summarizes the pivotal Phase

III results:

— Pursuant to the SPA, the primary endpoint of the Remoxy pivotal Phase III study was defined as mean decrease in pain intensity scores between Remoxy and placebo during the 12-week treatment period.

— The study achieved a statistically significant result in its primary endpoint (p less than 0.01).

— In addition, the study achieved statistically significant results in secondary endpoints such as Quality of Analgesia (p less than 0.01) and Global Assessment (p less than 0.01).

About Oxycodone Abuse

Please visit the U.S. Drug Enforcement Administration's website for more information:
http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycodone.htm

About Chronic Pain

Approximately 50 million Americans suffer with chronic pain, a distinct type of pain, often with no cure. It can affect an individual throughout his or her life, lasting several weeks, months, or even years at a time. The onset of chronic pain may be nociceptive (caused by ongoing tissue injury), neuropathic (caused by damage to the brain, spinal cord, or peripheral nerves), or disease specific (such as osteoarthritis or cancer).

Corporate Relationships

In December 2002, DURECT licensed to Pain Therapeutics, Inc. the right to develop and commercialize on a worldwide basis Remoxy and other oral sustained release drug candidates using the ORADUR technology which incorporate four specified opioid compounds. Under the license agreement, DURECT is reimbursed for formulation and other work performed under its agreement with Pain Therapeutics, and will receive additional payments if certain development and regulatory milestones are achieved with respect to the licensed drug candidates. In addition, if commercialized, DURECT will receive royalties for Remoxy and certain other licensed drug candidates of between 6.0% to 11.5% of net sales of the drug candidate depending on sales volume as well as a mark-up on DURECT's supply of key excipients used in the manufacture of the licensed drug candidates. Pain Therapeutics sublicensed the commercialization rights to Remoxy and other licensed drug candidates to King Pharmaceuticals in November 2005.

About ORADUR

ORADUR is a proprietary technology designed to transform short-acting oral capsule dosage forms into sustained release oral products, with the added benefit of being less prone to abuse than other controlled release dosage forms on the market today.

About DURECT Corporation

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including Remoxy, POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-Sufentanil. DURECT's proprietary (oral, transdermal and

injectable depot) delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit http://www.www.durect.com.

NOTE: ORADUR(TM), POSIDUR(TM), ELADUR(TM) and TRANSDUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. Remoxy(TM) is a drug candidate under development and has not been approved for commercialization by the US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding Remoxy, its attributes and its potential to be the first oxycodone on the market that deters common methods of abuse, the potential acceptance of the Remoxy NDA filing and granting of priority review by the FDA, the potential benefits of scientific and clinical testing data included in the Remoxy NDA and the potential milestone, royalties and other payments to DURECT from the development and commercialization of Remoxy 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, difficulties or delays in the development, testing, regulatory approval, production and commercialization of Remoxy, unexpected delays in the acceptance or review of NDA filing for Remoxy by the FDA, and unexpected adverse side-effects or inadequate therapeutic efficacy of Remoxy that could slow or prevent product approval or market acceptance (including the risk that current and past results of clinical trials are not necessarily indicative of future results of clinical trials). Further information regarding these and other risks is included in DURECT’s Form 10-Q dated May 8, 2008 under the heading “Risk Factors.”

SOURCE DURECT Corporation
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