ORADUR(TM) Technology Milestone: Remoxy(TM) (ORADUR-based oxycodone) Receives Special Protocol Assessment and Commences Pivotal Phase III

CUPERTINO, Calif., Feb. 17 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) reported today that Remoxy(TM), an abuse-resistant pain medicine under development based on DURECT's patented ORADUR(TM) technology incorporating the opioid oxycodone has successfully completed a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA) and that a pivotal Phase III trial is being commenced on Remoxy in 400 patients with severe chronic pain. The events were announced on February 16 by King Pharmaceuticals, Inc. (NYSE: KG), the company which will be commercializing Remoxy, if approved, and Pain Therapeutics, Inc. (Nasdaq: PTIE), DURECT's licensee of the rights to Remoxy and other ORADUR-based products incorporating oxycodone and three other opioid compounds.

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

"We are very pleased with development progress of Remoxy and the clarification of the pathway to regulatory approval afforded by the Special Protocol Assessment," said Jim Brown, D.V.M., President & CEO of DURECT. "If approved, we expect these products to generate significant value for our shareholders since DURECT will receive royalties based on net sales of Remoxy and other licensed ORADUR products of between 6.0% to 11.5% (depending on sales volume) and a manufacturing mark-up on key product excipients, in addition to payments upon achievement of development milestones and reimbursement of our development costs."

Dr. Brown continued, "We are also delighted with the continued advancement of our ORADUR technology platform, and are excited about its potential as a platform for numerous other innovative products given its unique combination of sustained-release and abuse-resistant properties. We look forward to developing additional innovative sustained release oral gel-cap products that utilize opioids not subject to our alliance with Pain Therapeutics and King and other active agents prone to abuse."

Special Protocol Assessment

A Special Protocol Assessment (SPA) from the FDA specifies the Phase III trial objective, design, clinical endpoints and analyses needed to support regulatory approval. These features are considered binding, i.e., the FDA will not later alter its perspective unless public health concerns unrecognized at the time of protocol assessment under this process are evident. For more information please visit the FDA website: www.fda.gov/CbER/gdlns/protocol.pdf.

Phase III Trial Details (as announced by Pain Therapeutics and King Pharmaceuticals)

Under the terms of the SPA for Remoxy, one pivotal Phase III trial is required to file a New Drug Application. The randomized, double-blinded, placebo-controlled, multi-center pivotal trial will enroll 400 patients with moderate-to-severe osteoarthritic pain in multiple U.S. clinical sites. Following a titration period, patients will be randomized to either Remoxy (10-80 mg daily) or placebo for 12 weeks. The primary endpoint is reduction in pain scores over three months compared to baseline. Patient accrual is expected to begin shortly and continue through year end 2006.

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 sustained 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. and King Pharmaceuticals, 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 development and license agreement between DURECT and Pain Therapeutics. 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. Pain Therapeutics has sublicensed the commercialization rights of Remoxy to King Pharmaceuticals. Oxycodone is the active drug ingredient in Remoxy and in the branded product OxyContin(R). OxyContin(R), the leading brand name opioid used in the treatment of moderate-to-severe pain, has U.S. sales of nearly $2 billion for the 12-months ending August 2005, according to IMS Health data. 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.

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. The company is developing pharmaceutical systems to deliver the right drug to the right place in the right amount at the right time to treat chronic and episodic diseases and conditions.

Forward Looking Statement

The statements in this press release regarding DURECT's and our collaborators' investigational products, development and clinical trial plans, commercial potential and possible economic returns 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' abilities to successfully enroll and complete clinical trials, complete the design, development, and manufacturing process development of the development product, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize the development product, as well as marketplace acceptance of the investigational product. 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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