Pain Therapeutics Receives Complete Response Letter From FDA for REMOXY(R)

CUPERTINO, Calif., Dec. 11 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) today reported that Pain Therapeutics, Inc. (Nasdaq: PTIE) has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for REMOXY(R), an abuse-resistant controlled-release form of oxycodone. Based on its review, the FDA has determined that the NDA is not approved in its present form.

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

According to King Pharmaceuticals, Inc. (NYSE: KG), Pain Therapeutics' commercial partner for REMOXY, the FDA believes additional non-clinical data will be required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval. Pain Therapeutics, King Pharmaceuticals, Inc. and their outside technical advisors are evaluating the FDA Complete Response Letter, will discuss the Letter with the FDA, and will provide an update when appropriate. Pain Therapeutics and King Pharmaceuticals remain diligently committed to their strategic alliance to develop and commercialize REMOXY and other abuse-resistant pain medications.

REMOXY is being developed by Pain Therapeutics under license from DURECT, and Pain Therapeutics has, in turn, sublicensed the commercialization rights for this drug candidate to King Pharmaceuticals. REMOXY, based on DURECT's ORADUR(TM) technology, is an investigational drug that is a unique, abuse-resistant, controlled release formulation of oxycodone for moderate-to-severe chronic pain.

About ORADUR(TM) Technology

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 (e.g. by crushing or water extraction) than other controlled release dosage forms on the market today.

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 the 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 of REMOXY and other licensed drug candidates to King Pharmaceuticals in November 2005

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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(R), 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: POSIDUR(TM), SABER(TM), ORADUR(TM), TRANSDUR(TM), and ELADUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have 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 potential attributes and statements related to plans by Pain Therapeutics and King Pharmaceuticals to discuss the Complete Response Letter with the FDA and provide an update when appropriate 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, the potential that FDA may not grant regulatory approval of REMOXY, difficulties or delays in the development, testing, regulatory approval, production and commercialization of REMOXY, 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 November 4, 2008 under the heading "Risk Factors."

SOURCE DURECT Corporation

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