REMOXY(R) NDA Update

CUPERTINO, Calif., July 7 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) today reported that King Pharmaceuticals, Inc. (NYSE: KG) and Pain Therapeutics, Inc. (Nasdaq: PTIE) have announced that King met with the Food and Drug Administration (FDA) on July 2, 2009 to discuss the Complete Response Letter regarding the New Drug Application (NDA) for REMOXY(R). According to King Pharmaceuticals and Pain Therapeutics, the outcome of the meeting last week provided King with a clear path forward to resubmit the REMOXY NDA and to address all FDA comments in the Complete Response Letter.

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

According to the King Pharmaceuticals / Pain Therapeutics press release, King now anticipates the resubmission of the NDA could occur mid-year 2010. King believes that the rate limiting step is the generation of six-month stability data, and no new clinical trials are required. King has stated that it remains committed to the development and commercialization of REMOXY and looks forward to working closely with the FDA toward approval of the product.

REMOXY, based on DURECT's ORADUR(TM) technology, is an investigational drug that is a unique, controlled release formulation of oxycodone for moderate-to-severe chronic pain designed to reduce potential risks of unintended use. In mid-2008, an NDA for REMOXY was accepted by the FDA and was granted Priority Review. In December 2008, Pain Therapeutics received a Complete Response Letter from the FDA. Subsequent to the receipt of the Complete Response Letter, King assumed full control of all activities related to the development of REMOXY.

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 alcohol 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, 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.

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 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 for resubmission of the REMOXY NDA, including the contents and timing of such resubmission, the generation of stability data as described above, the potential of FDA approving the REMOXY NDA, the timing and content of any potential update to be provided by Pain Therapeutics and King, as well as the potential royalty and other payments that may be received by DURECT from REMOXY and other described products 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 the REMOXY NDA resubmission may not adequately address all of FDA's concerns, 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 and tests are not necessarily indicative of future results of clinical trials and tests). Further information regarding these and other risks is included in DURECT's Form 10-Q dated May 7, 2009 under the heading "Risk Factors."

SOURCE DURECT Corporation

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