REMOXY(R) NDA Filing Accepted by FDA and Priority Review Granted

CUPERTINO, Calif., Aug. 12 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today that the US Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) of REMOXY(R) and granted Priority Review. The FDA typically grants Priority Review to drug candidates that have the potential to demonstrate significant improvements compared to marketed products. The FDA goal for completing review of a drug with Priority Review status is six months from the date the application was submitted. The REMOXY NDA was submitted to the FDA by Pain Therapeutics on June 10, 2008.

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

“We are pleased that the NDA has been accepted and that REMOXY will receive Priority Review,” 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’re delighted that our ORADUR(TM) technology has enabled the development of REMOXY, an investigational drug that has the potential to be the first oxycodone on the market that deters common methods of abuse.”

REMOXY is being developed by Pain Therapeutics (Nasdaq: PTIE) under license from DURECT, and Pain Therapeutics has, in turn, sublicensed the commercialization rights for this drug candidate to King Pharmaceuticals (NYSE: KG). REMOXY, an investigational drug, is a unique, abuse-resistant, controlled release 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.

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.

DURECT Forward-Looking Statement

The statements in this press release regarding REMOXY, its attributes, the timing of FDA review of the NDA and its potential to be the first oxycodone on the market that deters common methods of abuse 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 August 8, 2008 under the heading "Risk Factors."

SOURCE DURECT Corporation
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