Pfizer Receives Complete Response Letter from FDA for REMOXY®

CUPERTINO, Calif., June 24, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) today reported that Pfizer Inc. (NYSE: PFE) has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) for REMOXY®, a controlled-release form of oxycodone designed to discourage common methods of tampering. Pfizer stated that it is working to evaluate the issues described in the Complete Response Letter and plans to have further discussions with FDA around them.

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

“Pfizer has an experienced team of scientists dedicated to resolving the remaining issues,” stated James E. Brown, D.V.M., President and CEO of DURECT Corporation. “The misuse and abuse of pain medications is a widespread problem in this country and we will continue to support Pfizer in their efforts to address this important public health and safety issue.”

REMOXY, based on DURECT’s ORADUR® 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. Approximately 50 million Americans suffer from persistent pain each year, according to the American Pain Foundation.

About ORADUR® 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 resisting common methods of prescription drug misuse and abuse compared to other controlled release dosage forms on the market today.

Corporate Relationships

In December 2002, DURECT licensed to Pain Therapeutics, Inc. (Nasdaq: PTIE) 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. Pfizer completed its acquisition of King Pharmaceuticals in February 2011 and as a result has assumed the development and commercialization rights and obligations to REMOXY.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY®, POSIDUR(TM), ELADUR®, and TRANSDUR®-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.

DURECT Forward-Looking Statement

The statements in this press release regarding REMOXY, its potential attributes including potential benefits such as discouraging common methods of tampering, Pfizer’s on-going review and interactions with FDA regarding approval of the REMOXY NDA and the potential of resolving all outstanding regulatory concerns regarding REMOXY, and 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 Pfizer may not be able to adequately address all of FDA's concerns regarding the REMOXY NDA or there could be a delay in addressing such 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. Further information regarding these and other risks is included in DURECT's Form 10-Q dated May 5, 2011 under the heading "Risk Factors."

NOTE: POSIDUR(TM), SABER(TM), ORADUR®, TRANSDUR®, 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 U.S. Food and Drug Administration or other health authorities.

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