



REMOXY(R) New Drug Application Accepted by the FDA with PDUFA Goal Date of June 23, 2011

CUPERTINO, Calif., Jan. 27, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) today reported that the U.S. Food and Drug Administration (FDA) has accepted the resubmission of the New Drug Application (NDA) for REMOXY(R) by King Pharmaceuticals, Inc. (NYSE: KG) and the PDUFA goal date is June 23, 2011.

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

REMOXY, based on DURECT's ORADUR(R) 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(R) 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. In October 2010, Pfizer Inc. (NYSE: PFE) announced that it had entered into a definitive merger agreement to acquire King. Should that transaction be completed, Pfizer would assume the development and commercialization rights and obligations to REMOXY and to the other licensed ORADUR-based opioids.

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(R), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies may 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.durect.com.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), 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 U.S. 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 the expected PDUFA review date goal by the FDA, the potential of FDA approving the REMOXY NDA, the potential royalty and other payments that may be received by DURECT from REMOXY and other described products, and the potential acquisition of King by Pfizer 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, and that the Pfizer acquisition of King may not be completed. Further information regarding these and other risks is included in DURECT's Form 10-Q dated November 4, 2010 under the heading "Risk Factors."

SOURCE DURECT Corporation