



# DURECT Announces Issuance of U.S. Patents Covering ORADUR® Technology

## New Patents Broaden and Extend Protection for REMOXY® and other ORADUR-based Opioids

CUPERTINO, Calif., May 3, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced the issuance of four patents by the United States Patent and Trademark Office (USPTO) covering DURECT's ORADUR technology. These patents provide additional intellectual property protection for REMOXY (oxycodone) Extended-Release Capsules CII and other ORADUR-based opioids until at least 2025. 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.

"The four new patents expand on the intellectual property coverage afforded REMOXY and other ORADUR-based opioids, and the issuance of these patents indicates that the USPTO recognizes the unique aspects of our controlled release, tamper-resistant technology," stated James Brown, President and CEO of DURECT.

The four recently issued patents are U.S. Patent Nos. 8,133,507; 8,147,870; 8,153,152; and 8,168,217. The '507, '152, and '217 patents claim oral formulations comprising an opioid, such as oxycodone, and other components. The '870 patent claims methods of making opioid-containing formulations. Several more patent applications covering REMOXY and other ORADUR-based opioids are pending, including patent applications which, if granted, would result in patents expiring in 2028, plus any eligible patent term adjustments and extensions. In Europe, REMOXY and other ORADUR-based product candidates are covered by two granted patents expiring in 2016 and 2023, respectively, plus any eligible patent term extensions.

### About REMOXY®

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 that can be used to formulate a number of drug substances in a capsule dosage form to impart controlled delivery characteristics 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 (NYSE: PFE) 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™, 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.direct.com](http://www.direct.com).

### **DURECT Forward-Looking Statement**

The statements in this press release regarding issued and pending patent applications in the U.S. and Europe covering the ORADUR technology, REMOXY and other ORADUR-based product candidates, and the potential benefits and uses of REMOXY 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 risk of patent validity being challenged and not upheld, adverse decisions by regulatory agencies, including product non-approval, requests for additional information, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of REMOXY, the potential that the data that has been generated may not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of REMOXY, failure to manufacture, and commercialize or obtain marketplace acceptance of REMOXY and the risk of infringing patents held by other parties. Further information regarding these and other risks is included in DURECT's Form 10-K on March 2, 2012 under the heading "Risk Factors."

NOTE: POSIDUR<sup>™</sup>, SABER<sup>®</sup>, ORADUR<sup>®</sup>, TRANSDUR<sup>®</sup>, and ELADUR<sup>™</sup> 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.

SOURCE DURECT Corporation

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