Pfizer Proceeding with REMOXY® Development

CUPERTINO, Calif., Oct. 22, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today that Pfizer Inc. (NYSE: PFE) has stated that, having achieved technical milestones related to manufacturing, they will continue the development program for REMOXY® (oxycodone) Extended-Release Capsules CII. Following guidance received from the U.S. Food and Drug Administration (FDA) earlier this year, Pfizer announced that they will proceed with the additional clinical studies and other actions required to address the Complete Response Letter received in June 2011. These new clinical studies will include, in part, a pivotal bioequivalence study with the modified REMOXY formulation to bridge to the clinical data related to the original REMOXY formulation, and an abuse-potential study with the modified formulation. As previously disclosed, the complete response submission is not expected to occur prior to mid-2015.

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

“We are pleased that, after a thorough review and having achieved technical milestones, Pfizer is proceeding with development of REMOXY,” stated James Brown, President and CEO of DURECT. “We continue to believe that REMOXY could play an important role in serving the needs of chronic pain patients while potentially reducing the misuse and abuse of oxycodone.”

In addition, Pain Therapeutics, Inc. (Nasdaq: PTIE) has regained all rights from Pfizer with respect to the three other ORADUR-based opioid drug candidates (hydrocodone, hydromorphone and oxymorphone). Pain Therapeutics is now free to develop and commercialize these product candidates on its own or with a licensee. Investigational New Drug (IND) applications for these drug candidates are in place with the FDA. Pain Therapeutics has stated that they have not yet made a decision to develop or out-license the three product candidates.

About REMOXY

REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. Based on DURECT’s ORADUR® technology, which is covered by issued patents and pending patent applications owned by us, REMOXY is designed to discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse.

Corporate Relationships

In December 2002, DURECT licensed to Pain Therapeutics 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 with Pain Therapeutics, 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. In 2005, King Pharmaceuticals, Inc. entered into an agreement with Pain Therapeutics to develop and commercialize REMOXY. Pfizer obtained rights to REMOXY as part of its acquisition of King Pharmaceuticals in February 2011.

About DURECT Corporation

DURECT is a specialty pharmaceutica lcompany 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.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding REMOXY, the continued development of REMOXY by Pfizer, additional trials and studies, the potential resubmission of the NDA to the FDA, the potential regulatory approval of REMOXY by the FDA, 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 that additional trials and studies will not have satisfactory outcomes, the risk that Pfizer will discontinue development of REMOXY in the future, the risk of adverse decisions by regulatory agencies, including product non-approval, 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 submitted by Pfizer in response to the complete response letter will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of REMOXY, and the risk of obtaining marketplace acceptance of REMOXY, avoiding infringing patents held by other parties and securing and defending patents of our own, and managing and obtaining capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on August 6, 2013 under the heading "Risk Factors."

NOTE: ORADUR®, POSIDUR™, SABER®, TRANSDUR®, and ELADUR™ are trademarks of DURECT Corporation. 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

Matthew J. Hogan, Chief Financial Officer, DURECT 408-777-4936