DURECT Provides Update on REMOXYÂ® and POSIDURâ?¢ Programs

CUPERTINO, Calif., Oct. 27, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) reported today that Pfizer Inc. (NYSE: PFE) announced today that it has notified Pain Therapeutics, Inc. (Nasdaq: PTIE) that Pfizer has decided to discontinue its agreement to develop and commercialize REMOXYÂ® (oxycodone) Extended-Release Capsules CII, an investigational extended-release oral formulation of oxycodone. Pfizer will return all rights, including responsibility for regulatory activities, to Pain Therapeutics. As a result, Pain Therapeutics has the rights to develop and commercialize REMOXY on its own or with an alternative licensee. Pain Therapeutics had the rights to develop and commercialize this product candidate under a license from DURECT.

Pfizer further announced that it has concluded an internal review of the top-line results of five recently completed clinical studies required to address the Complete Response Letter received in June 2011 from the U.S. Food and Drug Administration (FDA), that Pfizer and Pain Therapeutics will work together for an orderly transition of REMOXY to Pain Therapeutics, and that Pfizer will continue ongoing activities under the agreement for the next six months until the scheduled termination date.

“We are surprised by Pfizer’s decision given the late stage of this program, and 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,” stated James Brown, President and CEO of DURECT. “With respect to POSIDUR, we had a face-to-face meeting with the FDA on September 23 to discuss what needs to be done to address the issues cited in the Complete Response Letter, and we are currently awaiting feedback from the FDA regarding our questions posed at the meeting.”

About REMOXY

REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Based on DURECT’s ORADURÂ® 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.

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. Pain Therapeutics filed the initial new drug application (NDA) for REMOXY in June 2008 and received a Complete Response Letter in December 2008. King Pharmaceuticals assumed full control of the development of REMOXY in March 2009 and filed a resubmission of the Remoxy NDA in December 2010, for which a Complete Response Letter was received by Pfizer in June 2011. Pfizer obtained rights to REMOXY as part of its acquisition of King Pharmaceuticals in February 2011. Pfizer notified Pain Therapeutics in late October 2014 that Pfizer had decided to discontinue its agreement to develop and commercialize REMOXY.

About POSIDUR

POSIDUR is an investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to provide up to three days of pain relief after surgery. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights, while at the same time we are preparing to be in a position to commercialize POSIDUR ourself in the U.S. in the event that we determine that is the preferred route of commercialization.

On February 12, 2014, we received a Complete Response Letter for POSIDUR from the FDA. Based on its review, the FDA has determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to

demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA has indicated that additional clinical safety studies need to be conducted.

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.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding REMOXY and POSIDUR, the continued development of REMOXY by Pain Therapeutics, cooperation of Pfizer and Pain Therapeutics for the next six months, Pain Therapeutics' decision to continue development of POSIDUR itself or with another licensee, additional trials and studies, the potential resubmission of the NDA for REMOXY and/or POSIDUR to the FDA, the potential regulatory approval of REMOXY and/or POSIDUR by the FDA, the FDA's responses to DURECT's questions from their face-to-face meeting, and the potential benefits and uses of REMOXY and POSIDUR 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 Pain Therapeutics 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 and/or POSIDUR, the potential that data submitted in response to these complete response letters will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of REMOXY and/or POSIDUR, and the risk of obtaining marketplace acceptance of REMOXY and POSIDUR, 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 for the quarter ending June 30, 2014 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.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-provides-update-on-remoxy-and-posidur-programs-385444463.html

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