



DURECT Announces FDA Acceptance of REMOXY® NDA, PDUFA Date of September 25, 2016

CUPERTINO, Calif., April 12, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced its licensee, Pain Therapeutics (Nasdaq: PTIE), has been informed by the U.S. Food and Drug Administration (FDA) that the New Drug Application (NDA) for REMOXY®, an abuse-deterrent formulation of extended-release oxycodone (CII) capsules, is sufficiently complete to permit a substantive review, and that September 25, 2016 is the target action date under the Prescription Drug User Fee Act (PDUFA).

About REMOXY (oxycodone capsules CII)

REMOXY, an investigational drug, is a unique long-acting oral formulation of oxycodone intended to manage 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 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.

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 that use the ORADUR technology and incorporate certain specified opioid compounds. DURECT is also reimbursed for formulation and other work performed under its agreement with Pain Therapeutics, will receive additional payments if certain development and regulatory milestones are achieved with respect to the licensed drug candidates, and will receive royalties of between 6.0% to 11.5% of net sales if REMOXY or the other licensed drug candidates are commercialized, as well as a mark-up on DURECT's supply of key excipients used in the manufacture of the licensed drug candidates.

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.

About DURECT Corporation

DURECT is a biopharmaceutical company focused on two areas of active drug development: new therapeutics based on its proprietary drug delivery platforms and new chemical entities derived from its Epigenomic Regulator Program. Its drug development expertise is being applied primarily to the fields of pain management, CNS disorders, acute organ injury and metabolic diseases such as NAFLD/NASH. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as improved abuse deterrence, convenience, adherence, efficacy and safety for small molecule and biologic drugs. Late stage development programs of this nature include POSIMIR™ (SABER®-Bupivacaine) and REMOXY® (ORADUR®-oxycodone). DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 development. DUR-928 is an endogenous small molecule that modulates lipid homeostasis, inflammation and cell survival. For more information, please visit www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding REMOXY and Pain Therapeutics' beliefs, plans and expectations regarding REMOXY, the anticipated PDUFA date, potential approval of an NDA for REMOXY by the FDA, the potential uses and features of REMOXY, the potential for a label claim for abuse deterrence, and the size and scope of target markets for 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 unexpected delays in the regulatory



review of, or adverse decisions by, the FDA, including product non-approval, further delays and additional costs due to requirements imposed by the FDA, the potential that the NDA will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of REMOXY (including the risk that current and past results of clinical trials and studies may be found to be insufficient for marketing approval), and the risks of obtaining marketplace acceptance of REMOXY, developments of products or technologies by current or future competitors, avoiding infringing patents held by other parties and securing and defending patents related to REMOXY. Further information regarding these and other risks is included under the heading "Risk Factors" in DURECT's Form 10-K dated March 1, 2016 filed with the Securities and Exchange Commission.

NOTE: POSIMIR[®], ORADUR[®] and SABER[®] are trademarks of DURECT Corporation. REMOXY, POSIMIR and DUR-928 are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/direct-announces-fda-acceptance-of-remoxy-nda-pdofa-date-of-september-25-2016-300250494.html>

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