DURECT Announces Resubmission of REMOXY® New Drug Application to the U.S. Food and Drug Administration

CUPERTINO, Calif., March 29, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced its licensee, Pain Therapeutics (Nasdaq: PTIE), has resubmitted the New Drug Application (NDA) for REMOXY® (oxycodone capsules CII) to the U.S. Food and Drug Administration (FDA). Pain Therapeutics has stated that they expect to be notified by the FDA of a Prescription Drug User Fee Act (PDUFA) action date within 30 days. The original REMOXY NDA has a Priority Review Designation.

“We are pleased to have the REMOXY NDA resubmitted to the FDA as we believe that REMOXY can play a meaningful role in controlling the pain of the large population of legitimate chronic pain patients who have a need for such products while at the same time incorporating abuse-deterrent properties that may play a role in reducing oxycodone misuse that is such a pressing public healthcare issue,” said James E. Brown, President and CEO of DURECT.

Chronic pain affects as many as 100 million Americans annually. When chronic pain is severe enough, patients are frequently prescribed long-acting opioid analgesics. Opioids (also called narcotics) include oxycodone, hydrocodone, hydromorphone, oxymorphone, morphine, fentanyl, methadone, and other members of this class. OxyContin®, a brand name oral extended-release oxycodone-based painkiller, accounted for approximately $2.4 billion in sales in the U.S. in 2014. While opioids are effective at treating pain, they are also widely misused and abused. The FDA has recently described this situation as the opioid abuse epidemic, and called for a far-reaching action plan to reassess the agency’s approach to opioid medications. One element of this action plan includes expanding access to, and encouraging the development of, abuse-deterrent formulations of opioid products.

About REMOXY

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.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 receipt of a 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 that the FDA will not accept Pain Therapeutics' resubmitted NDA, 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 in DURECT's Form 10-K dated March 1, 2016 filed with the Securities and Exchange Commission under the heading "Risk Factors."

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/durect-announces-resubmission-of-remoxy-new-drug-application-to-the-us-food-and-drug-administration-300242603.html

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