DURECT Announces FDA Advisory Committee Meeting for REMOXYÂ®

FDA's Tentative Date for Advisory Committee Meeting is August 5, 2016 and No Change to PDUFA Date of September 25, 2016

CUPERTINO, Calif., May 19, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that its licensee, Pain Therapeutics (Nasdaq: PTIE) has announced that an Advisory Committee of the U.S. Food and Drug Administration (FDA) will review the REMOXYÂ® New Drug Application (NDA), in a joint meeting of the FDA'sAnesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee tentatively scheduled for August 5, 2016. Pain Therapeutics also stated that the FDA advised them that the Prescription Drug User Fee Act (PDUFA) date for the REMOXY NDA of September 25, 2016 is unchanged.

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 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. The FDA has accepted for review the NDA for REMOXY. The REMOXY NDA has a PDUFA target date ofSeptember 25, 2016.

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 ORADURÂ® 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 POSIMIRÂ® (SABERÂ®-Bupivacaine) and REMOXYÂ® (ORADURÂ®-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 DURECT's beliefs, plans and expectations regarding REMOXY, including its potential uses and features, the FDA's review of the NDA for REMOXY, including the tentatively scheduled advisory committee meeting and the PDUFA date for the REMOXY NDA, and potential payments under DURECT's agreement with Pain Therapeutics

are forward-looking statements involving risks and uncertainties that can cause actual results to differ materiallyfrom 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, our potential failure to maintain our collaborative agreements with third parties and risks related to our (and our third party collaborators where applicable) ability to develop, manufacture and commercialize product candidates, 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-Q dated May 6, 2016 filed with the Securities and Exchange Commission.

NOTE: POSIMIRÂ®, ORADURÂ® and SABERÂ® 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-fda-advisory-committee-meeting-for-remoxy-300271513.html

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