



Results of FDA Advisory Committee Meeting for REMOXY® ER

CUPERTINO, Calif., June 26, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today reported that a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 14 to 3 against the approval of REMOXY® ER (oxycodone extended-release capsules) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The development and commercialization rights of REMOXY ER are held by Pain Therapeutics (Nasdaq: PTIE) under a license from DURECT. The Prescription Drug User Fee Act (PDUFA) date for completion of the review is August 7, 2018.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR-928, a new chemical entity in Phase 2 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include acute organ injury, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), and inflammatory skin conditions such as psoriasis and atopic dermatitis. DURECT's advanced oral and injectable delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late stage product candidate in this category is POSIMIR® (SABER®-Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery. Another late stage product candidate is REMOXY® ER (oxycodone), an investigational pain control drug based on DURECT's ORADUR® technology, for which the FDA has set a PDUFA (Prescription Drug User Fee Act) target action date of August 7, 2018. In addition, for the assignment of certain patent rights, DURECT may receive a milestone payment upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior's RBP-7000 investigational drug for schizophrenia, for which Indivior has submitted an NDA and for which the FDA has set a PDUFA target action date of July 28, 2018. For more information, please visit www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential benefits and uses of our drug candidates, including the potential use of REMOXY ER to treat pain, the potential payments receivable from Pain Therapeutics associated with approval and commercialization of REMOXY ER, the potential use of DUR-928 to treat NASH, PSC, acute organ injury or inflammatory skin diseases such as psoriasis, the potential use of POSIMIR to treat pain and the potential use of RBP-7000 to treat schizophrenia 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 risks that REMOXY ER will not receive product approval by the FDA and fail to achieve the performance milestones or commercial sales that trigger milestone payments or royalties, possible adverse events associated with the use of REMOXY ER, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of REMOXY ER, the risk that Pain Therapeutics will discontinue development of REMOXY ER, Pain Therapeutics' ability to obtain marketplace acceptance of REMOXY ER, the risk that the clinical trials of our other product candidates will not be successful, our ability to avoid infringing patents held by other parties and secure and defend patents of our own, and risks related to our ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K filed on March 8, 2018 under the heading "Risk Factors."

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928, RBP-7000, REMOXY ER and POSIMIR 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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