DURECT's Licensee Pain Therapeutics Receives Complete Response Letter from FDA for REMOXY® ER (oxycodone) Extended-Release Capsules CII

CUPERTINO, Calif., Aug. 6, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that its licensee, Pain Therapeutics (Nasdaq: PTIE) reported that it received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for Pain Therapeutics' New Drug Application (NDA) for REMOXY® ER (oxycodone) extended-release capsules CII, which concluded that "The data submitted in [the] NDA do not support the conclusion that the benefits of [REMOXY] Extended-Release Capsules outweigh the risks." Pain Therapeutics further announced a strategic reorganization to align its resources on advancing its drug and diagnostic assets in Alzheimer's disease.

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 candidateinDURECT'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 diseasessuch asnonalcoholic 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 candidatein this categoryisPOSIMIR®(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.In addition, for the assignment of certain patent rights, DURECT will receive a milestone payment upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior'sPERSERIS™ drug for schizophrenia, which was approved by the FDA in July 2018.For more information, please visit www.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 use of DUR-928 to treat NASH, PSC, acute organ injury or inflammatory skin diseases such as psoriasisand atopic dermatitis, and the potential use of POSIMIR to treat pain 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 risksthat REMOXY ER will not ever receiveproduct approval by theFDA and fail to achieve the performance milestones or commercial sales that trigger milestone payments or royalties, 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, the risk that the clinical trials of our other product candidates will not replicate the results of earlier clinical trials or animal studies and may 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 inDURECT's Form 10-Q filed on August 2, 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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