DURECT Announces Resubmission of REMOXY® ER New Drug Application by its licensee, Pain Therapeutics

CUPERTINO, Calif., Feb. 14, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that its licensee, Pain Therapeutics (Nasdaq: PTIE), reported yesterday that it has resubmitted the New Drug Application (NDA) for REMOXY® ER to the U.S. Food and Drug Administration (FDA). REMOXY ER is designed as an abuse-deterrent, extended release, capsule formulation of oxycodone, a prescription drug for severe pain. Pain Therapeutics stated that it expects a six-month review cycle by FDA, and that it expects to be notified by FDA of a Prescription Drug User Fee Act (PDUFA) date within 60 days.

About REMOXY

REMOXY ER, 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 ER 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 ER and other oral sustained release drug candidates that use the ORADUR technology and incorporate certain specified opioid compounds. DURECT is 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 REMOXY ER, and will receive royalties of between 6.0% to 11.5% of net sales if REMOXY ER is commercialized, as well as a mark-up on DURECT's supply of key excipients used in the manufacture of REMOXY ER.

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

DURECT is a biopharmaceutical company 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 schlerosing 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. 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.www.durect.com.

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. POSIMIR, DUR-928, RBP-7000 and REMOXY ER are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding the NDA resubmission of REMOXY ER, a potential six-month review cycle by the FDA for the NDA resubmission of REMOXY ER and the expectation that the FDA will assign a PDUFA date within 60 days, the potential benefits and uses of drug candidates, including the potential use of DUR-928 to treat PSC, NASH and other hepatic and renal diseases, acute organ injury or inflammatory skin conditions such as psoriasis and atopic dermatitis, POSIMIR to treat post-surgical pain, REMOXY ER to treat pain, Indivior's RBP-7000 to treat schizophrenia, and the potential milestone payment and earn-out payments receivable from Indivior, 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 the NDA resubmission of REMOXY ER will not be accepted by the FDA or result in product approval or will be met with delays, as well as possible adverse events associated with the use of POSIMIR, REMOXY ER and DUR-928, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR, REMOXY ER and DUR-928, and the possibility that studies of DUR-928, POSIMIR and REMOXY ER will not replicate results from earlier clinical trials. Further information regarding risks related to DUR-928, POSIMIR and REMOXY ER and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 2, 2017 under the heading "Risk Factors."

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