DURECT Announces Amendment to Licensing Agreement with Sandoz Related to POSIMIRÂ® (SABERÂ®-Bupivacaine)

CUPERTINO, Calif., May 9, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has entered into an amendment (the “Amendment”) to the development and commercialization agreement with Sandoz AG, a division of Novartis (NYSE: NVS), regarding POSIMIR$^{Â®}$ (SABER$^{Â®}$-bupivacaine) in the United States.

DURECT received an upfront payment from Sandoz of $20 million at the time the agreement between the two companies became effective in June 2017 and was initially eligible for up to an additional $43 million in payments based on successful development and regulatory milestones (of which $30 million is feasible following the results of the PERSIST Phase 3 clinical trial), and up to an additional $230 million in sales-based milestones. Sandoz received exclusive commercialization rights for POSIMIR in the U.S. upon regulatory approval with sole funding responsibility for commercialization activities. Sandoz has agreed to pay DURECT a tiered double-digit royalty on product sales for a defined period.

Pursuant to the amended agreement, DURECT is now eligible for up to $30 million in milestone payments based on NDA approval, and remains eligible for up to an additional $230 million in sales-based milestones. Each party, pursuant to the Amendment, is also permitted to develop or commercialize competing products. The Amendment also includes modifications to DURECT’s development obligations and to both parties’ termination provisions, including a right for DURECT to terminate for convenience prior to NDA approval. There is also a new termination fee payable to DURECT in the event that Sandoz terminates the agreement for convenience. The agreement between the two companies remains in full force and effect, except as expressly covered in the Amendment.

About POSIMIR$^{Â®}$ (SABER$^{Â®}$-Bupivacaine)

POSIMIR is an investigational extended-release depot utilizing DURECT’s patented SABER technology intended to continuously deliver bupivacaine to the surgical site for 72 hours, to provide up to three days of continuous pain relief after surgery. POSIMIR is a drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration (FDA) or other health authorities.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DURâ??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$^{Â®}$ (SABER$^{Â®}$-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$^{Â®}$ ER (oxycodone), an investigational pain control drug based on DURECT’s ORADUR$^{Â®}$ 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.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

POSIMIR to treat post-surgical pain, the potential milestone payments and royalties receivable fromSandoz, and the potential use of DUR-928 to treat NASH, PSC, acute organ injury or inflammatory skin diseases such as psoriasis 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 data for POSIMIR will not support a successful NDA resubmission or product approval, failure to achieve the performance milestones or commercial sales that trigger the referenced payments or royalties, possible adverse events associated with the use of POSIMIR, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR, our andSandoz's ability to obtain marketplace acceptance of POSIMIR, 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$^{Â®}$, SABER$^{Â®}$, and ORADUR$^{Â®}$ 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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