DURECT Announces FDA Approval of Indivior's PERSERIS™ (risperidone) Extended-Release Injectable Suspension for the Treatment of Schizophrenia in Adults

Approval triggers $5 million milestone payment to DURECT and future earn-out payments based on U.S. net sales

CUPERTINO, Calif., July 30, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that Indivior PLC (LON: INDV) has reported that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for PERSERIS™ (risperidone), which was formerly known as RBP-7000. As described by Indivior, PERSERIS is the first once-monthly subcutaneous risperidone-containing, long-acting injectable for the treatment of schizophrenia in adults.

"We are pleased to see PERSERIS receive FDA approval as an innovative treatment option for patients suffering from the very difficult medical condition of schizophrenia," stated Jim Brown, President and CEO of DURECT Corporation.

On September 26, 2017, DURECT entered into a patent purchase agreement whereby DURECT has assigned to Indivior UK Limited, an affiliate of Indivior PLC, certain patents that may provide further intellectual property protection for PERSERIS. In consideration for such assignment, Indivior made an upfront non-refundable payment to DURECT of $12.5 million. Indivior also agreed to make an additional $5 million payment to DURECT contingent upon NDA approval of PERSERIS, as well as quarterly earn-out payments that are based on a single digit percentage of U.S. net sales for certain products covered by the assigned patent rights, including PERSERIS. The patent rights include granted patents extending through at least 2026.

For additional information related to PERSERIS, please see the disclosures made by Indivior.

About DURECT

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 will receive a milestone payment based upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS drug for schizophrenia, which was approved in July, 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, 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 potential benefits and uses of drug candidates, including the potential

commercial sale of Indivior's PERSERIS to treat schizophrenia, and the potential earn-out payments receivable from Indivior, as well as the potential use of POSIMIR to treat post-surgical pain, the potential use of REMOXY ER to treat pain, and the potential use of DUR-928 to treat NASH, other liver diseases, acute organ injury or inflammatory skin conditions 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 that Indivior will not launch PERSERIS commercially or that it will not obtain market acceptance and meaningful sales, as well as possible adverse events associated with the use of PERSERIS, 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 POSIMIR, REMOXY ER and DUR-928 will not replicate results from earlier clinical trials. Further information regarding risks related to POSIMIR, REMOXY ER and DUR-928 and other risks related to DURECT is included in DURECT's Form 10-Q filed on May 9, 2018 under the heading "Risk Factors."

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