Commercial Launch Plans Announced for PERSERISâ?¢ (risperidone) Extended-Release Injectable Suspension for the Treatment of Schizophrenia in Adults

Indivior PLC Announces Plan for Commercial Launch in February 2019 with 50 Sales Representatives

CUPERTINO, Calif., Dec. 19, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that Indivior PLC (LON: INDV) stated on December 18, 2018 that it is moving ahead with the launch of PERSERISâ?¢ in the U.S. with a sales force consisting of approximately 50 representatives. While PERSERISâ?¢ has been available in the U.S. sinceNovember 19, 2018, Indivior stated that the commercial launch is scheduled to take place in February 2019. Indivior stated that its PERSERISâ?¢ team is currently engaged in creating payor access, growing prescriber awareness and interest, as well as establishing its INSUPPORTâ?¢ patient hub. Indivior reiterated its confidence in its peak net revenue goal for PERSERISâ?¢ of $200 to $300 million.

“We are pleased to see that Indivior is engaged in pre-launch activities, and we look forward to the commercialization of PERSERIS and the associated quarterly earn-out payments that we will receive in the coming years,” said James E. Brown, President and CEO of DURECT.

On September 26, 2017, DURECT entered into a patent purchase agreement whereby DURECT 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 made an additional $5 million payment to DURECT in August 2018 following NDA approval of PERSERIS in July 2018. DURECT is also entitled to 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 or visit www.perserishcp.com.

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 such as Alcoholic Hepatitis (AH), 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. Late stage product candidates in this category include POSIMIR® (bupivacaine extended release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, and ORADUR®-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights related to its drug delivery technology, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of PERSERISâ?¢ (risperidone), which was approved by FDA in July 2018 for the treatment of schizophrenia in adults and is owned and marketed by Indivior PLC. For more information, please visit www.www.durect.com.

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

DURECT Forward-Looking Statement
The statements in this press release regarding the potential commercial sale of Indivior's PERSERIS to treat schizophrenia, including the timing of U.S. launch, size of U.S. sales force, potential peak net revenue and earn-out payments receivable from Indivior, as well as the potential use of POSIMIR to treat post-surgical pain, and the potential use of DUR-928 to treat Alcoholic Hepatitis, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and Primary Sclerosing Cholangitis (PSC), and inflammatory skin conditions such as psoriasis and atopic dermatitis 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 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 and DUR-928, and the possibility that studies of DUR-928 will not replicate results from earlier preclinical or clinical trials. Further information regarding risks related to DUR-928 and POSIMIR and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 8, 2018 under the heading "Risk Factors."

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