DURECT Announces NDA Acceptance of Indivior's RBP-7000 Risperidone Monthly Depot

CUPERTINO, Calif., Dec. 13, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that Indivior PLC (LON: INDV) has reported that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for RBP-7000. RBP-7000 is an investigational, once-monthly injectable risperidone for the treatment of schizophrenia. Indivior PLC further reported that the FDA has set a PDUFA (Prescription Drug User Fee Act) target action date of July 28, 2018.

On September 26, 2017, DURECT entered into a patent purchase agreement whereby DURECT has assigned to Indivior UK Limited, an affiliate of Invidior PLC, certain patents that may provide further intellectual property protection for RBP-7000. In consideration for such assignment, Indivior has made an upfront non-refundable payment to DURECT of $12.5 million, and has also agreed to make an additional $5 million payment to DURECT contingent upon NDA approval of RBP-7000, 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 RBP-7000. The patent rights include granted patents extending through at least 2026.

About DURECT

DURECT is a biopharmaceutical company actively developing new therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 1 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, chronic metabolic diseases such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) and other liver diseases with both broad and orphan populations, and inflammatory skin conditions such as psoriasis. DURECT's advanced oral, injectable, and transdermal 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 more information, please visit www.www.durect.com.

About Indivior

Indivior is a global specialty pharmaceutical company with a 20-year legacy of leadership in patient advocacy and health policy while providing education on evidence-based treatment models that have revolutionized modern addiction treatment. The name is the fusion of the words individual and endeavour, and the tagline "Focus on you" makes Invidior's commitment clear. Indivior is dedicated to transforming addiction from a global human crisis to a recognized and treated chronic disease. Building on its global portfolio of opioid dependence treatments, Indivior has a strong pipeline of product candidates designed to both expand on its heritage in this category and address other chronic conditions and co-occurring disorders of addiction, including alcohol use disorder and schizophrenia. Headquartered in the United States in Richmond, VA, Indivior employs more than 900 individuals globally and its portfolio of products is available in over 40 countries worldwide. Visit www.indivior.com to learn more.

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 use of Indivior's RBP-7000 to treat schizophrenia, and the potential milestone payment and 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 the NDA submission of

RBP-7000 will not result in product approval, 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 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 November 2, 2017 under the heading "Risk Factors."

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