DURECT Announces Methydur Sustained Release Capsules Receive Marketing Authorization for ADHD in Taiwan

– ORADUR®-Methylphenidate ER now called Methydur Sustained Release Capsules in Taiwan

– Developed by Orient Pharma under a license to the ORADUR® technology from DURECT

CUPERTINO, Calif., Sept. 18, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that Orient Pharma Co., Ltd., its licensee for certain Asian and South Pacific countries, has informed DURECT that it has obtained marketing authorization from the Ministry of Health and Welfare in Taiwan for Methydur Sustained Release Capsules. Methydur Sustained Release Capsules are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) and will be available in three strengths (22 mg, 33 mg and 44 mg) in Taiwan. Orient Pharma also has stated that it expects to have Methydur Sustained Release Capsules commercially available in Taiwan in 2019, while seeking a partner in China and pursuing regulatory approvals in selected other countries where it has commercialization rights and a commercialization presence.

“We congratulate Orient Pharma on this new drug approval which will offer an alternative treatment for those patients suffering from ADHD in Taiwan,” said James E. Brown, President and CEO of DURECT Corporation. “We are pleased to see this first marketing approval for a product utilizing the ORADUR technology and the second recent approval of a product utilizing our patents.”

According to Orient Pharma, supporting the new drug application was a Phase 3, multi-center, randomized, double-blind, placebo controlled, two-way cross-over study designed to demonstrate the efficacy and safety of Methydur Sustained Release Capsules in children and adolescents with ADHD aged 6 to 18 years. There were 110 subjects enrolled in this study, of which 100 evaluable subjects completed the study. For the primary efficacy endpoint, Orient Pharma observed a statistically significant difference between Methydur Sustained Release Capsules and Placebo treatments in the mean change of total score for the Swanson, Nolan, and Pelham-IV (SNAP-IV) teacher form (p=0.0044 for the intent to treat population and p=0.0104 for the per protocol population). Orient Pharma’s safety analysis indicates that the incidence of adverse events with Methydur Sustained Release Capsules was similar to other approved Methylphenidate products.

About the DURECT – Orient Pharma Relationship

In August 2009, DURECT entered into a development and license agreement with Orient Pharma, a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan. In this agreement, DURECT granted to Orient Pharma the development and commercialization rights to ORADUR-Methylphenidate ER Capsule (Methydur Sustained Released Capsules) in certain defined Asian and South Pacific countries. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. If commercialized, DURECT will be entitled to receive a royalty on sales of Methydur Sustained Release Capsules by Orient Pharma. Orient Pharma has also committed to supply a portion of the commercial requirements in territories other than the United States for Methydur Sustained Release Capsules.

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 potential 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 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 such as 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. 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. In addition, for the assignment of certain patent rights, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was approved in July 2018. 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 benefits and uses of drug candidates, including the potential commercial sale of Orient Pharma's Methydur Sustained Release Capsules to treat ADHD and Indivior's PERSERIS to treat schizophrenia, the potential royalty payments receivable from Orient Pharma 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 Orient Pharma will not launch Methydur Sustained Release Capsules commercially in its territories or that it will not obtain market acceptance and meaningful sales, 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, Methydur Sustained Release Capsules, 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 August 2, 2018 under the heading "Risk Factors."

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