ORADUR®-Methylphenidate ER Capsule Achieves Primary Endpoint in Phase 3 Study in ADHD in Taiwan

– Statistically significant difference between ORADUR-Methylphenidate ER Capsule and placebo on SNAP-IV teacher form score

– Study drug was generally safe and well tolerated

CUPERTINO, Calif., Aug. 8, 2017 /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 a Phase 3 clinical study of ORADUR-Methylphenidate ER Capsule conducted in Taiwan has achieved positive results. ORADUR-Methylphenidate ER Capsule is an investigational drug candidate for the treatment of attention deficit hyperactivity disorder (ADHD).

“We congratulate Orient Pharma on the results of this trial and look forward to their pursuing a new drug application with the Taiwan Food and Drug Administration,” said James E. Brown, President and CEO of DURECT Corporation. “On our part, we intend to reach out with this Phase 3 data to potential development and commercialization partners for major markets not licensed to Orient Pharma.”

The Study

This was a Phase 3, multi-center, randomized, double-blind, placebo controlled, two-way cross-over study designed to demonstrate the efficacy and safety of ORADUR-Methylphenidate ER Capsule in children and adolescents with ADHD aged 6 to 18 years. There were 110 subjects enrolled in this study, of which 99 evaluable subjects completed the study. The primary efficacy measure in this study was to demonstrate superiority of ORADUR-Methylphenidate ER Capsule over placebo using the Swanson, Nolan, and Pelham-IV (SNAP-IV) teacher form score. The SNAP-IV rating scale contains 26 questions, classified as three components of ADHD symptoms (inattention, hyperactivity/impulsivity and oppositional defiant disorder).

For the primary efficacy endpoint, ORADUR-Methylphenidate ER Capsule was superior to placebo in a statistically significant manner (p=0.0044 for the intent to treat population and p=0.0032 for the per protocol population).

There were no serious adverse events in this pivotal study. Orient Pharma’s safety analysis indicates that the incidence of adverse events was generally consistent with other ADHD products.

About Attention Deficit Hyperactivity Disorder (ADHD)
ADHD is a neurobehavioral condition that is estimated to affect over 5 million (approximately 9%) of U.S. children ages 3-17, according to the U.S. Department of Health and Human Services. The prevalence of ADHD in Taiwan has been reported to be approximately 5-7% among school children. The principal characteristics of ADHD are inattention, hyperactivity, and impulsivity. The condition presents itself in childhood and can be life long as a significant number of children with ADHD continue to present symptoms as adults. It is estimated that over 50% of children with ADHD in the U.S. are being treated by medication, with stimulants such as amphetamine or methylphenidate as first-line treatments. U.S. sales of ADHD treatments were approximately $10.4 billion in 2016. The 2010 National Survey on Drug Use & Health estimates that 1.1 million Americans over the age of 12 abuse stimulants for euphoric highs and increased performance or wakefulness.

About ORADUR®-Methylphenidate ER Capsule

ORADUR-Methylphenidate ER Capsule is an investigational product candidate for the treatment of ADHD. This drug candidate is intended to provide once-a-day dosing with added tamper-resistant characteristics to address common methods of abuse and misuse of methylphenidate, a commonly prescribed first-line treatment for ADHD. ORADUR-Methylphenidate ER Capsule is a drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration, the Taiwan Food and Drug Administration

or other health authorities.

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, under which we granted to Orient Pharma development and commercialization rights in certain defined Asian and South Pacific countries to ORADUR-Methylphenidate ER Capsule. We retain rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. If commercialized, we will be entitled to receive a royalty on sales of ORADUR-Methylphenidate ER Capsule by Orient Pharma. Orient Pharma has committed to supply a portion of our commercial requirements in territories other than the United States for ORADUR-Methylphenidate ER Capsule.

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 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.

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 our drug candidates, including the potential use of ORADUR-Methylphenidate ER Capsule to treat ADHD with once-a-day dosing and tamper-resistant characteristics, the potential use of DUR-928 to treat NAFLD, NASH, other liver diseases, acute organ injury or inflammatory skin conditions such as psoriasis and the potential use of POSIMIR to provide 3 days of continuous pain relief after surgery 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 development program for ORADUR-Methylphenidate ER Capsule or POSIMIR will not support successful NDA submissions or product approvals, possible adverse events associated with the use of these product candidates, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of these product candidates, the ability to manufacture, commercialize and obtain marketplace acceptance of these product candidates, if approved, and 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-Q filed on May 10, 2017 under the heading "Risk Factors."

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