DURECT Announces Patient Enrollment in Phase 1b Clinical Trial of Oral DUR-928 in Patients with Non-Alcoholic Steatohepatitis (NASH)

CUPERTINO, Calif., March 27, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has commenced patient enrollment in a Phase 1b trial with oral DUR-928 in patients with NASH. DUR-928, the lead investigational product in the Company's Epigenetic Regulator Program, is an endogenous, first-in-class small molecule, which may have broad applicability in chronic hepatic diseases such as NASH, acute organ injuries such as alcoholic hepatitis (AH) and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

"NASH is a complex medical condition for which multimodal treatments are likely to be required to address the full range of NASH patients," stated Dr. Brent Tetri, Professor of Internal Medicine at Saint Louis University. "DUR-928 has been shown to have an excellent safety profile to date. As an endogenous molecule with a novel mechanism of action, it will be intriguing to see what biological signals are generated in this multi-dose study especially given what was previously reported in the single-dose study."

"Commencing patient enrollment in this multi-dose NASH trial is the third important milestone for DUR-928 so far in 2019," said James E. Brown, President and CEO of DURECT. "First we announced the advancement to the 90 mg dosing cohort in severe AH patients in our AH trial based on encouraging data in the 30 mg dosing cohorts, then commencement of dosing in the psoriasis trial, and now enrollment for daily dosing of DUR-928 in patients with NASH. We look forward to multiple DUR-928 readouts in 2019."

This is an open-label, Phase 1b study, evaluating three doses of oral DUR-928 (low, middle and high) administered daily for 28 consecutive days to evaluate safety, pharmacokinetics and signals of biological activity in patients with NASH.DURECT plans to enroll approximately 20 patients per dose group for a total of approximately 60 patients in the trial. The trial is being conducted at multiple clinical sites in the U.S. DURECT expects to announce initial data from this study in the second half of 2019.

In the Company's previous Phase 1b NASH study, reported at the European Association for the Study of the Liver (EASL) in April 2017, exploratory biomarker analysis demonstrated that a single oral dose of DUR-928 in NASH patients, at both dose levels tested (50 mg and 200 mg), resulted in statistically significant reductions from baseline of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, hsCRP and IL-18.

Key Opinion Leader (KOL) Call

On Wednesday, April 17, 2019 at 11:00am EST/8:00am PST, DURECT will be hosting a key opinion leader (KOL) call providing an overview of NASH and its progression, current treatment options and new treatments in development for NASH. The call will feature a presentation by KOL Brent Tetri, MD, Professor of Internal Medicine at Saint Louis University. DURECT will also provide an overview of the Company's development program for DUR-928 and Dr. Tetri will be available to answer questions after the presentations.

Dial-In & Webcast Information

Thursday, April 17 @ 11:00 am Eastern Time / 8:00 am Pacific Time

Domestic:	888-394-8218
International:	323-794-2149
Conference ID:	7990605
Webcast w/Slides:	**http://public.viavid.com/index.php?id=128731**

About NASH

Non-alcoholic fatty liver disease (NAFLD) is the most common form of chronic liver disease in both children and adults. It is estimated that NAFLD affects about 20% to 30% of adults and 10% of children in the United States. NASH, a more severe and

progressive form of NAFLD, is one of the most common chronic liver diseases worldwide, with an estimated prevalence of more than 10% of adults in the United States, Europe, Japan and other developed countries. No drug is currently approved for NAFLD or NASH.

About DURECT Corporation

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 (AH) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), 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, DURECT receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was commercially launched in February 2019. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the planned Phase 1b trial of DUR-928 in NASH patients, the potential of DUR-928 to show positive signals of biological activity in such trial, the potential use of DUR-928 to treat chronic hepatic diseases such as NASH, acute organ injuries such as alcoholic hepatitis (AH) and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis, the use of POSIMIR to treat post-surgical pain, the use of Indivior's PERSERIS™ to treat schizophrenia, as well as the potential commercial sales of Indivior's PERSERIS 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 risk of delays in the enrollment of the ongoing clinical trials of DUR-928 in NASH, AH and mild to moderate plaque psoriasis, potential adverse effects arising from the testing or use of DUR-928, the risk that the FDA may not approve the POSIMIR NDA, the risk that PERSERIS will not have a successful launch, our ability to avoid infringing patents held by other parties and secure and defend patents of our own patents, and our ability to manage and obtain capital to fund our operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K on March 8, 2019 under the heading "Risk Factors."

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SOURCE DURECT Corporation

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