DURECT Announces Completion of Enrollment in its Phase 2a Clinical Trial of DUR-928 in Psoriasis and 50% Enrollment in its Phase 1b DUR-928 Clinical Trial in NASH

CUPERTINO, Calif., Oct. 7, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has completed enrollment in its Phase 2a clinical trial of topical DUR-928 in patients with mild to moderate plaque psoriasis. The company also announced that it has now enrolled 30 of the planned 60 patients in its ongoing Phase 1b trial with oral DUR-928 in patients with non-alcoholic steatohepatitis (NASH).

“We are pleased that on the heels of completing the alcoholic hepatitis trial on schedule and announcing positive results, we have also achieved important enrollment milestones in our ongoing psoriasis and NASH trials,” saidJames E. Brown, President and CEO of DURECT. “With these two trials progressing as planned, we are approaching important data readouts for DUR-928 in these difficult to treat conditions.”

The company expects to announce top line data from the psoriasis trial by the end of this year. The NASH trial is on schedule to be completed in the first half of 2020 and the company plans to announce top line study results following completion of the trial.

About the DUR-928 Psoriasis Phase 2a Trial
The trial is a Phase 2a, randomized, double-blind, vehicle-controlled, multi-center, proof-of-concept study in which DUR-928 is applied topically once-daily for 28 days with a 28-day follow-up period in patients with mild to moderate plaque psoriasis. The trial is being conducted in the U.S. The plan was to enroll at least 20 patients to have 15 evaluable patients. At the time of this announcement, more than 20 patients have been enrolled. Each patient serves as their own control, applying DUR-928 to the plaque on one arm and the vehicle (placebo) to a similar plaque on the other arm. After the treatment period, patients will be followed for an additional four weeks. The primary efficacy endpoint is change in local psoriasis scores from baseline in the DUR-928-treated plaques compared to the vehicle-treated plaques.

About the DUR-928 NASH Phase 1b Trial
In March 2019 we began enrolling patients in a Phase 1b randomized and open-label clinical study being conducted at multiple centers in the U.S. to evaluate safety, pharmacokinetics (PK) and signals of biological activity of DUR-928 in NASH patients with stage 1-3 fibrosis. Patients take oral DUR-928, at one of three doses (50 mg QD, 150 mg QD and 300 mg BID), daily for 28 consecutive days and are then followed for 28 days. The plan is to enroll 20 patients per dose group (with 15 evaluable) for a total of approximately 60 patients in the trial. Key endpoints include safety, PK, and signals of biological activities, including clinical chemistry and biomarkers as well as liver fat content by imaging.

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 inDURECT’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. Key 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, a long-acting injectable SABER-based HIV product being developed with Gilead, 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 about DURECT, please visit www.www.durect.com.

NOTE: POSIMIR®, SABER® and ORADUR™ 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 plans, enrollment rates, timing to obtain data and complete data analyses from the Phase 2a trial of DUR-928 in patients with psoriasis and the Phase 1b trial of DUR-928 in patients with NASH are forward looking statements, which are subject to risks and uncertainties. These risks and uncertainties include, but are not limited to, the risk of delays in enrollment, or that the trials will not meet their respective endpoints or reveal adverse safety information. This press release also includes additional forward-looking statements, including regarding the potential use of DUR-928 to treat AH, AKI, chronic hepatic diseases such as NASH, and inflammatory skin disorders such as psoriasis and atopic dermatitis, as well as statements regarding the use of POSIMIR to treat post-surgical pain, the use of Methydur to treat ADHD, and potential earn-out payments from U.S. sales of PERSERIS. These forward-looking statements involve 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 potential adverse effects arising from the testing or use of DUR-928, the risk that results from earlier trials may not be replicated in future clinical trials, including in trials with larger numbers of patients, the risk that the FDA may not approve the POSIMIR NDA, the risk that PERSERIS and Methydur will not be successfully commercialized, 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-Q filed with the Securities and Exchange Commission on August 2, 2019 under the heading "Risk Factors."

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