DURECT Announces Completion of the 90 mg Severe Cohort and Dose Escalation Committee Approval to Commence 150 mg Dosing in Patients with Severe Alcoholic Hepatitis (AH) in its Ongoing DUR-928 Phase 2a AH Trial

CUPERTINO, Calif., June 18, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has completed dosing the 90 mg cohort of severe AH patients in its ongoing DUR-928 Phase 2a clinical trial, and that after reviewing safety and pharmacokinetic (PK) data from the completed cohorts, the Dose Escalation Committee (DEC) has approved commencement of dosing at the 150 mg level in severe AH patients. Enrollment for moderate AH patients to be dosed at the 90 mg level will continue in parallel to enrollment for severe AH patients to be dosed at the 150 mg level.

“Preliminary data from the completed cohort of severe AH patients dosed at 90 mg are consistent with the preliminary data from 30 mg and 90 mg patients we reported last month,” said James E. Brown, President and CEO of DURECT. “We are excited to be moving into the final dosing cohort for patients with severe AH and look forward to completing the trial and reporting the data at a future medical conference.”

About the Ongoing DUR-928 Alcoholic Hepatitis Phase 2a Trial

DURECT is conducting a Phase 2a clinical trial with intravenously administered DUR-928 in patients with AH. This is an open label, dose escalation (30, 90 and 150 mg), multi-center U.S. study that is enrolling patients with moderate and severe AH. Dose escalation may occur following review of safety and PK results of the prior dose level by a DEC. The target number of patients for the study is 4 moderate and 4 severe patients per dose group. The objectives include assessment of safety, PK and pharmacodynamic (PD) signals, including liver chemistry and biomarkers.

As reported on May 7 and 8, 2019 through a press release and key opinion leader conference call, preliminary clinical data from the first 10 AH patients dosed with DUR-928 demonstrated significant reductions from baseline of serum bilirubin levels and MELD scores, and significantly lower Lille scores compared to historical controls. In addition, DUR-928 was well tolerated and PK parameters were not affected by the severity of the disease.

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. 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 aboutDURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding plans, preliminary data and potential results from the ongoing Phase 2a trial of DUR-928 in patients with AH are forward looking statements, which are subject to risks and uncertainties. These risks and uncertainties include the risk that preliminary results may not predict the results for the full trial or for the outcomes of the patients whose data is reported. This press release also includes additional forward-looking statements, including regarding clinical trial plans for DUR-928, 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, that the remainder of the Phase 2a clinical trial of DUR-928 in AH patients does not replicate the preliminary results reported here, the risk of delays in the enrollment of the ongoing clinical trials of DUR-928 in AH, NASH and psoriasis, potential adverse effects arising from the testing or use of DUR-928, the risk that theFDA may not approve the POSIMIR NDA, the risk that PERSERIS and Methydur will not have successful commercial launches, 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 inDURECT's Form 10-Q filed with the Securities and Exchange Commission on May 7, 2019 under the heading "Risk Factors."

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