DURECT Corporation Announces First Patient Dosed in Phase 2b AHFIRM Study of DUR-928 in Severe Alcohol-Associated Hepatitis

CUPERTINO, Calif., Jan. 25, 2021 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has dosed the first patient in its AHFIRM randomized, double-blind, placebo-controlled, multi-center Phase 2b study to evaluate the safety and efficacy of DUR-928 in severe alcohol-associated hepatitis (AH) patients.

“We are excited to have begun dosing severe AH patients in the AHFIRM trial. There are no approved therapies indicated for treatment of AH and the average mortality rate in AH clinical trials at 90 days after admission to the hospital is 29%,” statedJames E. Brown, D.V.M., President and CEO of DURECT. “In our completed Phase 2a AH trial, all 19 patients dosed with DUR-928 survived the 28-day study period. In this much larger, placebo-controlled Phase 2b AHFIRM trial, we are evaluating DUR-928’s lifesaving potential in severe AH patients at 90 days compared to a control group that will receive placebo and standard of care. We believe that demonstration of a robust survival benefit in this trial may support an NDA filing.”

About the AHFIRM Clinical Trial – *Phase 2b study in subjects with **A**lcohol-associated **H**epatitis to evaluate sa**F**ety and eff**I**cacy of DU**R**-928 treat**M**ent **(AHFIRM)***

AHFIRM is a Phase 2b clinical trial evaluating the potential life-saving capacity of DUR-928 in patients with severe AH. AHFIRM is a randomized, double-blind, placebo-controlled, international, multi-center study to evaluate the safety and efficacy of DUR-928 in approximately 300 patients with severe AH. The study will be comprised of three arms of approximately 100 patients each: (1) DUR-928 (30 mg); (2) DUR-928 (90 mg); and (3) Placebo plus standard of care (SOC). SOC may include the use of methylprednisolone, a corticosteroid, at the discretion of the treating physician. Patients will receive an intravenous (IV) dose of DUR-928 or placebo (sterile water) on day 1 and a second IV dose on day 4 if they are still hospitalized. The primary outcome measure will be 90-day survival rate for patients treated with DUR-928 compared to those treated with placebo plus SOC. Secondary endpoints include 28-day survival, the rate of adverse events, Lille and MELD (prognostic scores), and time in the intensive care unit. The Company is targeting 40-50 clinical trial sites in the US and Europe. For more information, refer to ClinicalTrials.gov Identifier: NCT04563026

About Alcohol-Associated Hepatitis (AH)

Alcohol-Associated Hepatitis (also called Alcoholic Hepatitis or AH) is an acute form of alcohol-associated liver disease (ALD) associated with long-term heavy intake of alcohol, and often occurs after a recent period of increased alcohol consumption. AH is typically characterized by recent onset jaundice and hepatic failure. According to the Agency for Healthcare Research and Quality (AHRQ), a part of the US Department of Health and Human Services (HHS), there were over 122,000 hospitalizations for patients with AH in 2017. From a recent publication analyzing the mortality and costs associated with AH, the cost per patient is estimated at over $50,000 in the first year. ALD is one of the leading causes of liver transplants in the U.S., costing over $800,000 per patient. An analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients, showed the overall mortality from AH was 26% at 28 days, 29% at 90 days and 44% at 180 days after admission.

About DUR-928

DURECT’s lead drug candidate, DUR-928, is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival.

About DURECT Corporation

DURECT is a biopharmaceutical company committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. DUR-928, the company's lead drug candidate is being developed for the potential treatment of alcohol-associated hepatitis (AH) for which FDA has granted a Fast Track Designation, COVID-19 patients, and non-alcoholic steatohepatitis (NASH). DURECT's proprietary drug 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® (bupivacaine sustained-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery. For more information about DURECT, please visit www.www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development plans for DUR-928, including the potential use of DUR-928 to treat AH, plans for the AHFIRM trial and the potential for this Phase 2b trial to support an NDA, the potential use of DUR-928 to treat COVID-19 patients or NASH, and the potential use of POSIMIR to provide 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 AHFIRM trial will take longer to conduct than anticipated, will not confirm the results from earlier clinical or pre-clinical trials, or will not demonstrate the safety or efficacy or the life saving potential of DUR-928 in a statistically significant manner, the risk that the FDA will not approve POSIMIR or approve POSIMIR with a limited label, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or the Company's other product candidates, potential adverse effects arising from the testing or use of our drug candidates 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 November 3, 2020 under the heading "Risk Factors."

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 and POSIMIR are investigational drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication.

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SOURCE DURECT Corporation

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