DURECT Corporation Announces Design of Phase 2b AH Study (AHFIRM)

Phase 2b study in subjects with Alcoholic Hepatitis to evaluate safety and efFIcacy of DUR-928 treatMent (AHFIRM)

CUPERTINO, Calif., Sept. 22, 2020 /PRNewswire/ — DURECT Corporation (NASDAQ: DRRX) today announced the study design for the Phase 2b AHFIRM clinical trial of DUR-928 in severe alcoholic hepatitis (AH) patients.

AHFIRM is a randomized, double-blind, placebo-controlled, international, multi-center Phase 2b 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 40-45 clinical trial sites in the US and Europe and anticipates trial initiation in October.

“We are pleased to announce the design and pending initiation of this important clinical trial,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Following on the very encouraging results from our Phase 2a AH trial, we believe that the Phase 2b AHFIRM trial will provide a robust evaluation of the safety and potential life-saving capacity of DUR-928 in severe AH patients, who desperately need an effective therapy.”

About Alcoholic Hepatitis (AH)

AH is an acute form of alcoholic 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 117,000 hospitalizations for patients with AH in 2016. 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.

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 in clinical development for the potential treatment of alcoholic hepatitis (AH), COVID-19 patients with acute liver or kidney injury, and nonalcoholic 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 extended-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 and other acute organ injuries, including in COVID-19 patients, as well as chronic liver diseases, such as 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 start of the AHFIRM trial or other trials will be delayed due to COVID-19 or other factors, that the AHFIRM trial will take longer than expected and may not replicate results from earlier trials, that the clinical trial of DUR-928 in COVID-19 patients is delayed or stopped because of changes to the standard of care, the availability of alternative therapies, required protocol changes or lack of available patients, the risk that clinical trials of DUR-928 do not demonstrate the safety or efficacy 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, our potential failure to maintain our collaborative agreements with third parties 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 August 4, 2020 under the heading "Risk Factors."

 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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Corporate Contact: Mike Arenberg , DURECT, Chief Financial Officer, +1-408-346-1052, mike.arenberg@durect.com Media Contact: Alison Chen, LifeSci Communications, +1-646-876-4932, achen@lifescicomms.com