# DURECT Corporation Announces DUR-928 Granted FDA Fast Track Designation for Treatment of Alcoholic Hepatitis

CUPERTINO, Calif., Dec. 16, 2020 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to DUR-928 for the treatment of alcoholic hepatitis (AH, also known as alcohol-associated hepatitis). AH is an acute, life-threatening form of alcohol-associated liver disease (ALD). DUR-928 is the lead investigational product candidate in DURECT's Epigenetic Regulator program.

"Fast Track Designation highlights the life-threatening nature of AH and the lack of therapeutic options for this devastating condition," said Norman L. Sussman, M.D., Chief Medical Officer of DURECT Corporation. "As an endogenous epigenetic regulator, DUR-928 is a new class of therapeutics. We are very encouraged by the promising clinical data from our Phase 2a trial in which 100% of AH patients treated with DUR-928 survived the 28-day follow-up period compared to a 26% historical 28-day death rate. We look forward to initiating our Phase 2b trial shortly and working with the FDA to bring DUR-928 to the many patients in need as soon as possible."

The FDA grants Fast Track Designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track Designation can benefit from early and frequent communication with the agency in addition to a rolling submission of the marketing application, with the objective of getting important new therapies to patients more quickly.

**About Alcoholic Hepatitis (AH)**
AH is an acute form of alcohol-associated liver disease (ALD) that may occur after months or years of excess alcohol consumption, often after a recent period of intense 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.

**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 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 POSIMIRÂ® (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 November 3, 2020 under the heading "Risk Factors."

NOTE: POSIMIRÂ® and SABERÂ® 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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