Data Presentation Today at The Liver Meeting® 2021 Shows Increasing Hospital Admissions for Alcohol-Associated Hepatitis (AH) in the U.S.

AH hospitalizations increased by approximately 4.8% per year between 2015 and 2018

Approximately 80% of AH patients who died while hospitalized had acute kidney failure

CUPERTINO, Calif., Nov. 12, 2021 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced the presentation of data at the American Association for The Study of Liver Diseases (AASLD) The Liver Meeting® 2021 showcasing an increase of hospitalizations for alcohol-associated hepatitis (AH) in the U.S. of approximately 19% (from 110,085 in 2015 to 131,510 in 2018) or approximately 4.8% per year between 2015 and 2018.

“The prevalence of AH has been the subject of considerable interest. This study presents the most recent data of AH-related hospitalizations between 2015-2018,” said Suthat Liangpunsakul, M.D., M.PH., professor of Medicine in the Division of Gastroenterology and Hepatology and Department of Medicine at Indiana University, who is the presenter of this poster. “These patients represent a severely ill population with a high risk of death. Effective therapy for severe and hospitalized AH patients is currently lacking, and is a significant unmet medical need.”

Examination of data from AH patients who died during hospitalization highlighted that a high percentage of them had serious comorbidities: including acute kidney failure (80.2%), cirrhosis (69.1%), ascites (56.5%), sepsis (51.9%), coagulopathy (46.0%), and hepatic encephalopathy (42.1%). Additionally, total healthcare cost per hospitalization episode for AH patients was high for those who died, averaging $151,500 vs. $56,000 for survivors during the hospitalization.

The study analyzed more than seven million hospital stays annually from approximately 1,000 U.S. hospitals using the Nationwide Inpatient Sample (NIS) database. Patients hospitalized with a primary or secondary diagnosis of AH were identified using ICD-9 (Q1-Q3 2015) and ICD-10 (Q4 2015, 2016-2018) codes.

Norman Sussman, M.D., Chief Medical Officer at DURECT, added, “Given what we know about the disease and comorbidities associated with AH, effective treatments should ideally address the underlying pathophysiology in order to prevent disease progression. While previous attempts to treat AH have focused on one aspect of liver failure, we are excited with the potential of our epigenetic regulator candidate, larsucosterol (also known as DUR-928) to improve inflammation, cell death, and tissue regeneration in severe AH. This compound was remarkably effective in our Phase 2a trial, which encouraged us to proceed with a multinational randomized clinical trial, named AHFIRM, that is currently under way.”

The poster is available to attendees of The Liver Meeting® 2021 today and throughout the meeting ending November 15, 2021 after which, it will be available on the DURECT website under “DUR-928 Publications” here: DURECT | DUR-928 Publications.

About alcohol-associated hepatitis (AH)
AH is a life-threatening acute alcohol-associated liver disease (ALD) often caused by chronic heavy alcohol use and a recent period of increased alcohol consumption (e.g., a binge). It is characterized by severe inflammation and destruction of liver tissue (i.e., necrosis), potentially leading to life-threatening complications, including liver failure, acute renal injury and multi-organ failure. There are no FDA approved therapies for AH and the overall average mortality of AH patients in clinical trials has been reported to be 26% at 28 days, 29% at 90 days and 44% at 180 days. Stopping alcohol consumption is not sufficient for recovery in many moderate and severe patients and the use of treatments to reduce liver inflammation, such as corticosteroids, are limited by contraindications and have been shown to provide no survival benefit at 90 days or 1 year. While liver transplantation is becoming more common for alcoholic liver disease patients, including AH for patients, the procedure involves a long waiting period, a burdensome selection process and costs more than $875,000 on average.

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. Larsucosterol (also known as DUR-928), the Company's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes which are elevated and associated with hypermethylation found in AH patients. Larsucosterol is in clinical development for the potential treatment of alcohol-associated hepatitis (AH) for which FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis (NASH) is also being explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved. Full prescribing information about POSIMIR, including the Boxed Warning, can be found at www.posimir.com. 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 the potential for larsucosterol (also known as DUR-928) to treat patients with AH, NASH, multiple acute organ injury, chronic liver diseases and other diseases, ongoing clinical trials of larsucosterol, the potential benefits of Fast Track Designation, and the commercial potential of POSIMIR 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 clinical trial of larsucosterol in AH takes longer to conduct than anticipated due to COVID-19 or other factors, the risk that clinical trials of larsucosterol, including AHFIRM, do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy or the lifesaving potential of larsucosterol in a statistically significant manner, the risk that Fast Track Designation for larsucosterol in AH may not lead to faster FDA review or an approval, risks that we or a third-party licensee may not commercialize POSIMIR successfully, if at all, 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, 2021 under the heading "Risk Factors."

 Larsucosterol (DUR-928) is an investigational drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication. Full prescribing information for POSIMIR, including its Boxed Warning, can be found at www.posimir.com.

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Corporate Contact – Mike Arenberg, DURECT, Chief Financial Officer, +1-408-346-1052, mike.arenberg@durect.com; Media Contact – Mónica Rouco Molina, PhD, LifeSci Communications, +1-929-469-3850, mroucomolina@lifescicomms.com