

# DURECT Corporation to Present Additional Clinical Data from DUR-928 Studies in NASH (Phase 1b) and in Hepatic Impairment (Phase 1) at Upcoming International Liver Conference 2021 (EASL)

CUPERTINO, Calif., June 9, 2021 /PRNewswire/ — <u>DURECT Corporation</u> (Nasdaq: DRRX) today announced it will present two posters at the 2021 <u>International Liver Conference (EASL)</u> to be held virtually June 23-26, 2021.

The first poster will discuss additional efficacy signals from a Phase 1b clinical study of orally administered DUR-928 in nonalcoholic steatohepatitis (NASH) patients. Previously reported <u>data</u> showed that DUR-928 was well tolerated at all three doses evaluated, 50mg QD, 150mg QD, and 300mg BID (600mg/day) with overall improvement from baseline observed in liver enzymes, serum lipid profiles, liver fat by imaging, and biomarkers of liver health. The poster will feature additional efficacy signal data including liver stiffness by transient elastography (TE) and magnetic resonance elastography (MRE), liver fibrosis marker, pro-C3, and ELF scores, as well as insulin resistance (HOMA-IR).

A second poster will provide data from a Phase 1 study assessing the safety, tolerability, pharmacokinetics (PK) of DUR-928 in subjects with moderate (Child-Pugh B scores) and severe (Child-Pugh C scores) hepatic impairment (HI), who received a single oral dose of 200mg DUR-928.

#### **Poster Presentation Details:**

Title: Efficacy Signals of 4-Week Oral DUR-928 in NASH Subjects

Poster #: 1198

Presenter: Eric Lawitz, M.D., Vice President, Scientific and Research Development, Texas Liver Institute

Date/Time: June 24-26, 2021

**Poster Presentation Details:** 

Title: Safety and pharmacokinetics of DUR-928 in hepatic function impaired subjects

Session: 668

Presenter: Jaymin Shah, Ph.D., Executive Director, Clinical Pharmacology and Pharmacokinetics at DURECT

Date/Time: June 24-26, 2021

Copies of the posters will be available on DURECT's corporate website here at the conclusion of the conference.

### **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 alcohol-associated hepatitis (AH) for which FDA has granted a Fast Track Designation. The Company is conducting a double-blind, placebo-controlled Phase 2b clinical trial called AHFIRM, evaluating DUR-928's lifesaving potential compared to the current standard of care in patients with severe AH. 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 now FDA-approved. Full prescribing information about POSIMIR, including the Boxed Warning, can be found at <a href="https://www.posimir.com">www.posimir.com</a>. For more information about DURECT, please visit <a href="https://www.www.durect.com">www.www.durect.com</a> and follow us on Twitter <a href="https://twitter.com/DURECTCorp">https://twitter.com/DURECTCorp</a>.

## **DURECT Forward-Looking Statement**

The statements in this press release regarding the potential for DUR-928 to treat patients with AH, NASH, and other diseases, multiple acute organ injury, ongoing and planned clinical trials of DUR-928, 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 DUR-928 in AH



takes longer to conduct than anticipated due to COVID-19 or other factors, the risk that clinical trials of DUR-928, 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 DUR-928 in a statistically significant manner, 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 May 5, 2021 under the heading "Risk Factors."

NOTE: POSIMIR<sup>®</sup> and SABER<sup>®</sup> are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. 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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### **SOURCE DURECT Corporation**

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