DURECT Announces DUR-928 Phase 2a Alcoholic Hepatitis Study Results Selected for Late-Breaking Oral Presentation at The Liver MeetingÂ® 2019

Study Results Were Selected for Inclusion in the “Best of The Liver Meeting” Summary Slide Presentation

Poster Comparing DUR-928 Data to Historical Control Will Also be Presented

CUPERTINO, Calif., Oct. 21, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today that the results from the recently completed Phase 2a study of DUR-928 in patients with alcoholic hepatitis (AH) have been selected for an oral presentation as part of the late-breaking session of The Liver MeetingÂ® 2019, the annual meeting of the American Association for the Study of Liver Diseases (AASLD), taking place on November 8-12, 2019, in Boston. This late-breaking abstract was one of only 29 late-breaking abstracts selected out of a total of approximately 3,000 abstracts that were accepted for presentation at the meeting. Additionally, the study results were selected for inclusion in the ‘Best of The Liver Meeting’ summary slide presentation in the alcohol-related liver disease category. Tarek Hassanein, M.D., one of the trial’s principal investigators, will deliver the oral presentation of the detailed trial results.

In a separate poster presentation, Craig McClain, M.D., will present additional comparative data from the Phase 2a clinical trial of DUR-928 and a control group from a contemporaneous AH trial conducted at University of Louisville.

“We look forward to Drs. Hassanein and McClain’s respective presentations of the positive results of our recently completed Phase 2a trial of DUR-928 in patients with alcoholic hepatitis at this year’s Liver Meeting, which is among the most prestigious gatherings of scientists and health care professionals dedicated to preventing and curing liver disease,” said James E. Brown, President and Chief Executive Officer of DURECT. “These compelling data provide strong rationale for continued development, and we plan to initiate a Phase 2b study for this difficult-to-treat and life-threatening condition next year.”

Oral Late-Breaker Presentation Details:

Title: Safety and Efficacy of DUR-928: A Potential New Therapy for Acute Alcoholic Hepatitis
Date: Tuesday, November 12, 2019
Time: 8:30 am Eastern Time
Location: Auditorium, Hynes Convention Center
Session Title: Late-Breaking Abstract Oral Session II
Presentation Type: Oral, Late-Breaker Session
Publication Number: LO9

Poster Presentation Details:

Title: DUR-928 Therapy of Acute Alcoholic Hepatitis: A Pilot Study
Date: Sunday, November 10, 2019
Time: Noon â?? 2:00 pm Eastern Time
Location: Hynes Convention Center, Hall B
Presentation Type: Poster Presentation
Publication Number: 1376

About the DUR-928 Alcoholic Hepatitis Phase 2a Trial

Patients with moderate and severe AH were treated with intravenously administered DUR-928 in this open label, dose escalation, multi-center, U.S., Phase 2a clinical trial. Final enrollment was 19 patients comprised of: 8 patients (4 moderate and 4 severe) dosed at 30 mg, 7 patients (3 moderate and 4 severe) dosed at 90 mg and 4 patients (4 severe) dosed at 150 mg. The study objectives included assessment of safety, PK and pharmacodynamic (PD) signals, including liver chemistry and biomarkers.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DURâ??928, a new chemical entity in Phase 2 development, is the lead candidate inDURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include acute organ injury such as alcoholic hepatitis (AH) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), and inflammatory skin conditions such as psoriasis and atopic dermatitis.DURECT's advanced oral and injectable delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. Key product candidates in this category include POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, a long-acting injectable SABER-based HIV investigational product being developed with Gilead. For more information aboutDURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

This press release includes forward-looking statements, including plans to conduct a Phase 2b study of DUR-928 in patients with alcoholic hepatitis next year, the potential use of DUR-928 to treat AH, AKI, chronic hepatic diseases such as NASH, and inflammatory skin disorders such as psoriasis and atopic dermatitis, as well as statements regarding the use of POSIMIR to treat post-surgical pain and the development of a SABER-based HIV investigational product. These forward-looking statements involve 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 risk of delays in the commencement of the Phase 2b trial of DUR-928 in AH, future trials of DUR-928 in AH may not yield positive results, potential adverse effects arising from the testing or use of DUR-928, the risk that the FDA may not approve the POSIMIR NDA, our ability to meet milestones in the development of an injectable SABER-based HIV investigational product and the risk that Gilead will terminate the development of this product, our ability to avoid infringing patents held by other parties and secure and defend patents of our own patents, and our ability to manage and obtain capital to fund our operations and expenses. Further information regarding these and other risks is included inDURECT's Form 10-Q filed with the Securities and Exchange Commission on August 2, 2019 under the heading "Risk Factors."

NOTE: POSIMIR® and SABER®, are trademarks of DURECT Corporation. DUR-928 and POSIMIR are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities

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SOURCE DURECT Corporation

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