DURECT Corporation Announces Top-Line Results from Phase 2a Clinical Trial in Patients with Psoriasis

CUPERTINO, Calif., Jan. 2, 2020 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced the results from its Phase 2a clinical trial of DUR-928 in patients with mild to moderate plaque psoriasis. Twenty-two patients completed the study, applying DUR-928 topically to the plaque on one arm and the vehicle (placebo) to a similar plaque on the other arm daily for 28 days.

DUR-928 did not demonstrate a benefit over vehicle (placebo) based on Investigator's Global Assessment (IGA), which was the scoring system for the primary analysis, or in any of the secondary analyses. Daily topical application of DUR-928 was well tolerated with no meaningful differences in adverse events between the treatment and vehicle (placebo) groups. There were no AEs attributed to the study drug.

"Based on the top-line data, we do not plan to continue development of topical DUR-928 in psoriasis," saidJames E. Brown, President and CEO of DURECT. "With the recently announced positive results from our Phase 2a alcoholic hepatitis trial, our focus moving forward with DUR-928, will be on completing the NASH trial in the first half of this year and initiating the Phase 2b AH trial in the middle of the year."

About the DUR-928 Psoriasis Phase 2a Trial
The trial was a Phase 2a, randomized, double-blind, vehicle-controlled, multi-center, proof-of-concept study in which DUR-928 was applied topically once-daily for 28 days with a 28-day follow-up period in patients with mild to moderate plaque psoriasis. The trial was conducted in the U.S. Each patient served as their own control, applying DUR-928 to the plaque on one arm and the vehicle (placebo) to a similar plaque on the other arm. After the treatment period, patients were followed for an additional four weeks.

About DURECT Corporation

DURECT is a biopharmaceutical company actively developing therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?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 AH and acute kidney injury (AKI) and chronic hepatic diseases such as NASH. 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, and 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

The statements in this press release regarding the potential benefits and uses of DUR-928 to treat AH and about other potential uses of DUR-928 to treat NASH, AKI and other diseases, the potential use of POSIMIR to treat post-operative pain, and the potential development of a long-acting injectable SABER-based HIV product with Gilead 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 risk of delays in clinical trials or adverse safety events from patients administered with DUR-928, the risk that the ongoing clinical trial of DUR-928 in NASH does not successfully achieve its endpoints, the risk that placebo controlled studies of DUR-928 required for regulatory approval will not replicate results from open label clinical trials or trials with small numbers of patients or historical controls, the risks that the long-acting injectable SABER-based HIV investigational product being developed with Gilead will not succeed or that Gilead will abandon this program, the risk that the FDA Advisory Committee will not recommend approval of POSIMIR or that the FDA will not approve POSIMIR, and the risk of

delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of any of our product candidates. Further information regarding these and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 5, 2019 under the heading "Risk Factors" and in subsequent reports that we file with the Securities and Exchange Commission.

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. 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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