DURECT Announces Initiation of DUR-928 Dosing in Patients

Single-Ascending-Dose Study in NASH Patients

CUPERTINO, Calif., Jan. 11, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has initiated a single-ascending-dose Phase 1b clinical trial with DUR-928 in patients with nonalcoholic steatohepatitis (NASH). DUR-928 is an endogenous, small-molecule, new chemical entity (NCE), which may have broad applicability in metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and NASH, and in acute organ injuries such as acute kidney injury (AKI).

“We are excited to have the DUR-928 Chronic Metabolic Disease program advance into patient studies,” saidJames E. Brown, President and CEO of DURECT. “DUR-928 has demonstrated no adverse events in our previous studies with healthy volunteers. Gathering data from NASH patients in this trial will position the program for subsequent clinical studies.”

Phase 1b Oral Study
This Phase 1b trial of DUR-928 is a dose ranging, single-ascending-dose safety and pharmacokinetic study of DUR-928 of subjects with NASH and matched control subjects. This study will be conducted in three successive cohorts evaluating three single-dose levels of oral DUR-928. After a PK/safety review at each dose, the study can proceed to a successively higher dose. Assuming all three cohorts are dosed, the study will comprise approximately 48 subjects, of which approximately 30 will have received DUR-928. The study is being conducted in Australia and we anticipate that it will be completed in the first half of 2016.

About DURECT Corporation

DURECT is a biopharmaceutical company focused on two areas of active drug development: new therapeutics based on its proprietary drug delivery platforms and new chemical entities derived from its Epigenomic Regulator Program. Its drug development expertise is being applied primarily to the fields of pain management, CNS disorders, acute organ injury and metabolic diseases such as NAFLD/NASH. DURECT’s proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as improved abuse deterrence, convenience, adherence, efficacy and safety for small molecule and biologic drugs. Late stage development programs of this nature include POSIMIR® (SABER®-Bupivacaine) and REMOXY® (ORADUR®-oxycodone). DURECT’s Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 development. DUR-928 is an endogenous small molecule that modulates lipid homeostasis, inflammation and cell survival. For more information, please visit www.www.durect.com.

About DURECT’s Epigenomic Regulator Program

DURECT’s Epigenomic Regulator Program is a collaborative effort now in its fourth year between DURECT and the Department of Internal Medicine at Virginia Commonwealth University (VCU), the VCU Medical Center, and the McGuire VA Medical Center. During the course of this program, a number of compounds that may have therapeutic utility have been identified, including the lead molecule DUR-928. DURECT holds the exclusive worldwide right to develop and commercialize DUR-928 and related molecules discovered in the program. Several clinical indications are currently under exploration, including orphan and non-orphan diseases that are both acute and chronic in nature.

DURECT Forward-Looking Statement

The statements in this press release regarding DURECT’s Epigenomic Regulator Program and product candidate DUR-928, including the attributes, potential therapeutic effects for DUR-928 and other compounds identified during the course of the program, our development plans for DUR-928, and the timing of clinical trials, as well as the potential of our other products in development, 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, DURECT’s ability to design, enroll, conduct and complete clinical trials, whether additional human trials for DUR-928 will demonstrate biological activity shown in animal trials and/or will identify safety issues, DURECT’s ability to complete the design, development, and manufacturing process development of DUR-928 and other NCE product candidates, obtain product and manufacturing approvals from regulatory agencies

and manufacture and commercialize product candidates, and achieve marketplace acceptance of product candidates. Further information regarding these and other risks is included in DURECT's Form 10-Q dated November 3, 2015 filed with the Securities and Exchange Commission under the heading "Risk Factors."

NOTE: POSIMIR$^{â?¢}$ is a trademark of DURECT Corporation. REMOXY, POSIMIR and DUR-928 are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-announces-initiation-of-dur-928-dosing-in-patients-300201770.html

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