DURECT Announces Positive Phase 1 Data for DUR-928

Initial Phase 1 Safety Studies Successfully Completed, Positioning for the Start of Patient Studies in 2016

CUPERTINO, Calif., Jan. 6, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced the successful completion of a Phase 1 clinical trial with an injectable formulation of DUR-928 intended for acute use indications. 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 nonalcoholic steatohepatitis (NASH), and in acute organ injuries such as acute kidney injury (AKI).

“It’s nice to cap off a solid year of progress in 2015 by reporting the successful conclusion of this Phase 1 study of DUR-928 for acute use indications,” said James E. Brown, President and CEO of DURECT. “During 2015 more than 75 healthy volunteers received DUR-928 given either orally or through injection at varying doses in excess of endogenous levels, with no treatment related adverse events reported. Building on our learnings from 8 animal models that were previously reported, we now look forward to beginning patient studies in our chronic metabolic and acute use programs in 2016.”

Phase 1 Injectable Study

The Phase 1 trial of DUR-928 began as a single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of 4 doses DUR-928 when administered through an intramuscular injection. The 24-subject study evaluated DUR-928 in four cohorts of healthy volunteers receiving DUR-928 (n = 16 on drug, 8 on placebo) at escalating doses that resulted in peak plasma concentrations over 100 fold higher than endogenous levels. DUR-928 was well-tolerated at all dose levels, with no treatment-related adverse events reported and plasma levels were dose proportional.

Before the highest dose was added to the single-ascending-dose study, we proceeded to a multi-dose cohort including 10 healthy volunteers, in which study participants received DUR-928 for 5 consecutive days (n = 8 on drug, 2 on placebo) with what at the time was our highest dose in the prior study. No treatment related adverse events were reported, no subjects withdrew from the study, no accumulation in plasma concentrations were observed with repeat dosing, and the pain scores and injection site reactions were minimal.

Future Development Plans

DURECT is now positioned to commence patient trials in 2016 with DUR-928 and is currently finalizing protocols with the assistance of our scientific consultants. We plan to conduct the first two such studies in Australia. We will be providing more detail on these studies in the near future.

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 and nature of future 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™ 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.

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Matthew J. Hogan, Chief Financial Officer, DURECT 408-777-4936