DURECT Announces Initiation of DUR-928 Multi-Dose Phase 1 Study

CUPERTINO, Calif., March 30, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has initiated a multi-dose Phase 1 clinical trial of an oral formulation of DUR-928, the lead molecule in DURECT's Epigenomic Regulator Program. DUR-928 is an endogenous, small-molecule, new chemical entity (NCE) that may have broad applicability in metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). It may also play an important role in protecting against acute kidney injury (AKI) and other types of acute organ injury.

"Following the successful completion of our Phase 1 oral, single-dose study of DUR-928, we have now begun enrollment for a Phase 1 multiple-ascending-dose trial," said James E. Brown, President and CEO of DURECT. "This trial will provide valuable information on multi-dose pharmacokinetics that will be important as we continue moving toward Phase 2 planned for next year."

Phase 1 Multi-Dose Study

This Phase 1 trial is a single-site, randomized, double-blinded, placebo-controlled, multiple-ascending-dose study to evaluate the safety, tolerability, and pharmacokinetics of DUR-928 when orally administered once daily for 5 consecutive days to healthy volunteers. The 20-subject study will evaluate DUR-928 in 2 consecutive 10-subject cohorts, the first receiving DUR-928 at a lower dose and the second at a higher dose.

About DUR-928

DUR-928 is an endogenous, orally bioavailable small molecule that modulates the activity of several nuclear receptors that play an important regulatory role in lipid homeostasis, inflammation, and cell survival. A systems biology study involving over 23,000 genes showed that DUR-928 modulates the activity of more than 240 genes, including ACC, FAS, HMGR, Cyp7A1, LXR, PPAR?, NF?B/I?B, TNF?, IL-1?, IL-6, COX-2, PCSK9, and others.

The biological activity of DUR-928 has been demonstrated in 6 different animal disease models, 3 representing acute toxic or ischemic organ injury (kidney and liver) and 3 representing chronic disorders of hepatic lipid accumulation and dysfunction (NAFLD/NASH). Animal pharmacokinetics and toxicity studies have shown DUR-928 to be orally bioavailable and safe at all doses tested to date. An injectable formulation, envisioned for use in acute conditions, is currently undergoing animal testing.

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.

About DURECT Corporation

DURECT is a specialty pharmaceuticals company with expertise in drug discovery, drug delivery and drug development, applying those skills primarily to therapeutics in the fields of pain management, acute organ injury and metabolic diseases. 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 REMOXY® and POSIDUR™. DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 clinical testing. DUR-928 is an endogenous small molecule that is an epigenomic modulator of cellular activities involved in lipid homeostasis, metabolic disease, inflammation and cell survival. For more information, please visit www.www.durect.com.

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 and commercial potential 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 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-K dated March 3, 2015 filed with the Securities and Exchange Commission under the heading "Risk Factors."

NOTE: POSIDUR™ is a trademark of DURECT Corporation. REMOXY, POSIDUR 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-multi-dose-phase-1-study-300057159.html

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