DURECT Announces Patient Dosing in Phase 2a Trial of DUR-928 in Primary Sclerosing Cholangitis (PSC)

CUPERTINO, Calif., Feb. 26, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has commenced patient dosing in a Phase 2a clinical trial of DUR-928 in patients with primary sclerosing cholangitis (PSC). DUR-928, the lead investigational product in our Epigenetic Regulator Program, is an endogenous, first-in-class small molecule, which may have broad applicability in several hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and other disorders of the liver such as PSC, in acute organ injuries such as acute liver and kidney injury, and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

“There is a clear unmet medical need to find effective medical therapy in PSC and prevent progression to end stage liver disease, so we look forward to seeing how these patients respond when treated with this orally administered endogenous small molecule,” stated Dr. Kidist K. Yimam, Medical Director, Autoimmune Liver Disease Program at California Pacific Medical Center, Department of Hepatology and Liver Transplantation, San Francisco, CA. This is one of 15 sites planned for this study and the first site to enroll a patient.

“We are pleased to have started dosing the first of several DUR-928 Phase 2 studies planned for this year in an orphan patient population that has no approved treatment at this time,” said James E. Brown, President and CEO of DURECT. “We believe that data generated from this trial will be informative for future PSC trials and for other liver conditions such as NASH.”

The Phase 2a trial will be a randomized, open label study with two cohorts (a low dose cohort of 10 mg and a high dose cohort of 50 mg), in which patients (n = 20 per cohort) will receive oral dosing of DUR-928 for 4-weeks with follow-up for an additional four-weeks. The objectives of this study include safety, pharmacokinetic (PK) and pharmacodynamic (PD) markers, including the percent change from baseline of serum alkaline phosphatase (ALP) and other biomarkers. As an open label study, we expect to generate data during the course of 2018. Additional information on the trial design, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier NCT03394781.

On February 26, 2018 at 12:00 pm Eastern Time, there will be a key opinion leader webcast on the topic of PSC which will include Dr. Keith Lindor as a featured speaker as well as representatives of DURECT.

Dial-In & Webcast Information
Monday, February 26 @ 12pm Eastern Time / 9am Pacific Time

Domestic:	888-394-8218
International:	323-701-0225
Conference ID:	8794595
Webcast w/Slides:	https://viavid.webcasts.com/starthere.jsp?ei=1180471&tp_key=e5438d992d

About PSC

PSC is a chronic liver disease characterized by a progression of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. Over time, PSC leads to liver failure, infections and tumors of the bile duct or liver, ultimately requiring liver transplant. There is no approved treatment for PSC at this time. DURECT has received orphan drug designation for DUR-928 to treat patients with PSC. DURECT believes that data generated from this trial will be relevant to other chronic liver diseases involving inflammation, fibrosis, and cholestasis.

About DURECT Corporation

DURECT is a biopharmaceutical company 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 in DURECT’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, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and PSC, 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. One late stage product candidate in this category is POSIMIR® (SABER®-Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery. Another late stage product candidate is REMOXY® ER (oxycodone), an investigational pain control drug based on DURECT's ORADUR® technology. In addition, for the assignment of certain patent rights, DURECT may receive a milestone payment upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior's RBP-7000 investigational drug for schizophrenia, for which Indivior has submitted an NDA and for which the FDA has set a PDUFA target action date of July 28, 2018. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the Phase 2a trial of DUR-928 in PSC, including trial plans and potential results, the potential benefits and uses of drug candidates, including the potential use of DUR-928 to treat PSC, NASH and other hepatic and renal diseases, acute organ injury or inflammatory skin conditions such as psoriasis and atopic dermatitis, POSIMIR to treat post-surgical pain, REMOXY ER to treat pain, Indivior's RBP-7000 to treat schizophrenia, and the potential milestone payment and earn-out payments receivable from Indivior, 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 risks that the NDA submission of RBP-7000 will not result in product approval, as well as possible adverse events associated with the use of POSIMIR, REMOXY ER and DUR-928, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR, REMOXY ER and DUR-928, and the possibility that studies of DUR-928, POSIMIR and REMOXY ER will not replicate results from earlier clinical trials. Further information regarding risks related to DUR-928, POSIMIR and REMOXY ER and other risks related to DURECT is included in DURECT's Form 10-Q filed on November 2, 2017 under the heading "Risk Factors."

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. POSIMIR, DUR-928, RBP-7000, REMOXY ER and ORADUR-Methylphenidate ER are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

View original content:http://www.prnewswire.com/news-releases/durect-announces-patient-dosing-in-phase-2a-trial-of-dur-928-in-primary-sclerosing-cholangitis-psc-300603773.html

SOURCE DURECT Corporation

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