DURECT Announces Patient Dosing in Phase 2a Trial of DUR-928 in Alcoholic Hepatitis

CUPERTINO, Calif., April 25, 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 alcoholic hepatitis (AH). 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 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 acute alcoholic hepatitis, so we look forward to seeing how these patients respond when treated with this intravenously administered endogenous small molecule,” stated Dr. Lance Stein, MD, Piedmont Atlanta Hospital. This is one of 5 sites planned for this study and the first site to enroll a patient.

“We are pleased to have started dosing the second of several DUR-928 Phase 2 studies planned for this year in a patient population that has no novel effective treatments at this time,” said James E. Brown, President and CEO of DURECT.

The Phase 2a trial is an open label, dose escalation study conducted in two parts. Part A will include patients with moderate AH (as determined by MELD scores) and Part B will include patients with severe AH. The study will be conducted using three dose levels (30 mg, 90 mg and 150 mg) in Part A, with sequential dose escalation following review of safety and pharmacokinetics (PK) results of the prior dose level. Patients will receive DUR-928 by intravenous infusion, and the dose may be adjusted in Part B based on the findings from Part A. Patients will be enrolled at multiple clinical sites in the United States and the target number of participants to complete the study is 24-36. The objectives of this study are safety and PK. Pharmacodynamic (PD) signals will also be monitored, including liver biochemistry, MELD and Lille scores, 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 NCT03432260.

About Alcoholic Hepatitis

Alcoholic hepatitis is a syndrome characterized by progressive inflammatory liver injury associated with long-term heavy intake of alcohol, and involves a spectrum that ranges from mild injury to severe, life threatening injury. The prevalence of alcoholic hepatitis has not been accurately determined, but it is believed to occur in 10-35% of heavy drinkers. There were over 320,000 hospitalizations related to alcoholic hepatitis in the United States in 2010, and the hospitalization costs amounted to nearly $50,000 per patient.

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 Primary Sclerosing Cholangitis (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, for which the FDA has set a PDUFA target action date of August 7, 2018. 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 alcoholic hepatitis, 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 toDURECT is included in DURECT's Form 10-K filed on May 8, 2018 under the heading "Risk Factors."

 DUR-928, RBP-7000, REMOXY ER 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.

View original content:http://www.prnewswire.com/news-releases/durect-announces-patient-dosing-in-phase-2a-trial-of-dur-928-in-alcoholic-hepatitis-300635848.html

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