DURECT Announces Patient Dosing in Phase 2a Proof-of-Concept Clinical Trial of Topical DUR-928 in Patients with Mild to Moderate Plaque Psoriasis

CUPERTINO, Calif., March 21, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced it has commenced patient dosing in a Phase 2a proof-of-concept trial with topical DUR-928 in patients with mild to moderate plaque psoriasis. DUR-928, the lead investigational product in the Company's Epigenetic Regulator Program, is an endogenous, first-in-class small molecule, which may have broad applicability in chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), acute organ injuries such as alcoholic hepatitis (AH) and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

"As topical agents continue to be the mainstay of treatment for patients suffering from mild to moderate plaque psoriasis, especially localized plaque psoriasis, it is important to investigate a topical agent with a novel mechanism of action," stated Dr.Howard Maibach, Professor of Dermatology at the University of California San Francisco. "Should the results be positive, DUR-928 should be studied in additional inflammatory skin diseases."

"Commencing patient dosing in this proof-of-concept psoriasis trial is an important milestone in line with our focus for DUR-928 in 2019, which is to produce data with the potential to create significant commercial and partnering value," saidJames E. Brown, President and CEO of DURECT.

In this Phase 2a, randomized, double-blind, vehicle-controlled proof-of-concept clinical trial, DUR-928 will be applied topically once-daily for four weeks in patients with mild to moderate plaque psoriasis. The trial is being conducted at multiple clinical sites in the U.S. Twenty patients are planned to be enrolled to obtain approximately 15 evaluable patients. Patients will serve as their own controls, applying DUR-928 to the plaque on one arm and the vehicle to a similar plaque on the other arm. After the treatment period, patients will be followed for an additional four weeks. The primary efficacy endpoint will be change in local psoriasis scores from baseline in the DUR-928-treated plaques compared to that in the vehicle-treated plaques. We expect to announce top line data from this study in the second half of 2019. Additional information on the trial design, including eligibility criteria and site locations, can be found at https://clinicaltrials.gov/ using the NCT Identifier NCT 03837743.

DURECT previously conducted an exploratory Phase 1b trial in psoriasis patients (9 evaluable patients) in Australia. The trial was randomized, double-blinded, placebo and self-controlled, using a micro-plaque assay with intralesional injections of DUR-928. The results were encouraging and warranted advancing into the current proof-of-concept trial with topically applied DUR-928.

Key Opinion Leader (KOL) Call

On Friday, March 29, 2019 at 11:00am EST/8:00am PST, DURECT will be hosting a KOL call providing an overview of psoriasis and the treatment landscape for topical medications in psoriasis. The call will feature a presentation by KOL Howard Maibach, MD, Professor of Dermatology and practicing dermatologist at the University of California San Francisco (UCSF). DURECT will also provide an overview of the Company's development program for DUR-928 and Dr. Maibach will be available to answer questions after the presentations.

Dial-In & Webcast Information
Friday, March 29 @ 11am Eastern Time / 8am Pacific Time

Domestic:	888-254-3590
International:	323-994-2093
Conference ID:	3271109
Webcast w/Slides:	http://public.viavid.com/index.php?id=133666

About Psoriasis

Psoriasis is an inflammatory skin disease and an immune-mediated condition that causes the body to make new skin cells in days rather than weeks. In the United States, there are about 150,000 new cases of psoriasis every year and it affects an estimated 7.5 million Americans. According to the International Federation of Psoriasis Associations (IFPA), nearly 3% of the world's population has some form of psoriasis or about 125 million people. Psoriasis causes itchiness and irritation and may be painful. There is no cure for psoriasis, but treatment can ease symptoms. Approximately 80% of patients with psoriasis have localized disease, which can be treated with topical therapies. As such, topical agents remain the mainstay of psoriasis treatment.

About DURECT Corporation

DURECT is a biopharmaceutical company actively 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 such as Alcoholic Hepatitis (AH) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), 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. Late stage product candidates in this category include POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, and ORADUR®-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights, DURECT receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was approved in July 2018 and commercially launched in February 2019. For more information, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding the planned Phase 2a trial of DUR-928 in mild to moderate plaque psoriasis, the potential of DUR-928 to show positive signals of biological activity in such trial, the potential use of DUR-928 to treat chronic hepatic diseases such as NASH, acute organ injuries such as alcoholic hepatitis (AH) and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis, the use of POSIMIR to treat post-surgical pain, the use of Indivior's PERSERIS™ to treat schizophrenia, as well as the potential commercial sales of Indivior's PERSERIS 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 risk of delays in the commencement and enrollment of the planned clinical trial of DUR-928 in mild to moderate plaque psoriasis, potential adverse effects arising from the testing or use of DUR-928, the risk that the FDA may not approve the POSIMIR NDA, the risk that PERSERIS will not have a successful launch, our ability to avoid infringing patents held by other parties and secure and defend patents of our own patents, and our ability to manage and obtain capital to fund our operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K on March 8, 2019 under the heading "Risk Factors."

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