DURECT Announces FDA Advisory Committee Meeting to Review POSIMIR® for the Treatment of Post-Surgical Pain

CUPERTINO, Calif., Oct. 2, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today that the U.S. Food and Drug Administration (FDA) has notified the Company that its Class 2 NDA resubmission for POSIMIR® (bupivacaine extended-release solution) will be discussed at a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC). The meeting is tentatively scheduled for January 16, 2020. The FDA had previously assigned a user fee goal date of December 27, 2019; a new user fee goal date has not been assigned.

DURECT commissioned the advisory services of Dr. Lee S. Simon to lead the Company's preparation efforts to prepare for the advisory committee meeting. Dr. Simon is a physician and research scientist who served as the FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products from 2001 to 2003, and is now a Principal at SDG, LLC, an FDA advisory firm.

"We look forward to a productive discussion with the advisory committee," stated James E. Brown, President and CEO of DURECT. "If approved, we believe that POSIMIR could help address an important need for new long-acting, non-opioid pain products in the post-operative pain setting."

About POSIMIR

POSIMIR is the Company's investigational post-operative pain relief depot product that utilizes DURECT's patented SABER® technology. POSIMIR is designed to be administered directly into the surgical site to deliver bupivacaine for up to three days after surgery. POSIMIR has not been approved by the FDA for marketing in the U.S. for any indication.

About the POSIMIR Clinical Development Program

The POSIMIR clinical development program was designed to evaluate the safety and efficacy of a single dose of POSIMIR to treat post-surgical pain for up to three days.

In two completed adequate and well-controlled clinical trials, conducted in patients undergoing inguinal hernia repair and subacromial decompression (shoulder) surgeries respectively, POSIMIR demonstrated a significant decrease in pain and opioids consumed over the 0-72 hour period following surgery as compared to placebo. DURECT believes that these completed trials support the safety and efficacy of POSIMIR in post-operative pain and meet the requirements to be considered pivotal clinical trials.

In all, the Company has completed 16 clinical trials in the POSIMIR program, involving over 1,400 patients, over 850 of whom received POSIMIR, with the remainder in control groups. DURECT believes this is a sufficiently sized safety database. DURECT further believes that, with data from the PERSIST trial included, there may now be sufficient data to address FDA's issues raised in the CRL.

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. Key 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, a long-acting injectable SABER-based HIV investigational product being developed with Gilead, 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 commercially launched in February 2019. For more information about DURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding future events and expectations, including without limitation, the anticipated advisory committee meeting for POSIMIR, potential regulatory approval of POSIMIR by the FDA, the potential uses and benefits of POSIMIR, as well as statements about potential uses and benefits of DUR-928 and DURECT's oral and injectable delivery technologies, and potential revenues from 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 risks that the FDA advisory committee meeting will be delayed, that the committee will vote against approval of POSIMIR or make other unfavorable votes and/or statements about POSIMIR, that the FDA will require additional trials or additional information regarding POSIMIR, and the risk that the FDA may not approve the POSIMIR NDA. Additional risks include the risk that potential adverse effects may arise from the testing or use of DUR-928, that Gilead will discontinue the development of the SABER-based long-acting HIV investigational drug product, that ORADUR-Methylphenidate ER may not be commercially successful in territories where it is approved or approved in other territories, that Indivior will not generate significant sales of PERSERIS, that DURECT may not avoid infringing patents held by other parties or be unable to secure and defend its own patents, and DURECT'S ability to manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on August 2, 2019 under the heading "Risk Factors."

NOTE: POSIMIR®, SABER® and ORADUR™, are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928, POSIMIR and ORADUR-Methylphenidate ER Capsules are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities. Full prescribing information for PERSERIS, including BOXED WARNING, and Medication Guide can be found at www.perseris.com.

View original content: http://www.prnewswire.com/news-releases/durect-announces-fda-advisory-committee-meeting-to-review-posimir-for-the-treatment-of-post-surgical-pain-300929450.html

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