DURECT Completes Enrollment in PERSIST, Phase 3 trial for POSIMIR®

Top-Line Data on Track for Q4 2017

CUPERTINO, Calif., June 22, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that patient enrollment has been completed in PERSIST, the pivotal Phase 3 clinical trial of POSIMIR® (SABER®-Bupivacaine), an investigational locally acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery.

“The early completion of enrollment in PERSIST is an important milestone for our POSIMIR development program,” saidJames E. Brown, President and CEO of DURECT Corporation. “We look forward to completing patient follow-up visits during the third quarter and announcing top-line data in the fourth quarter of this year.”

In May 2017, DURECT signed a development and commercialization agreement with Sandoz AG, a division of Novartis, covering the United States. Under the terms of the agreement, Sandoz made an upfront payment to DURECT of $20 million following review under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976, with the potential for up to an additional$43 million in development and regulatory milestones, up to an additional $230 million in sales-based milestones, as well as a tiered double-digit royalty on product sales in the United States. DURECT remains responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval.

About PERSIST

PERSIST is a Phase 3 clinical trial consisting of patients undergoing cholecystectomy (gallbladder removal) surgery. Part 1 of PERSIST consists of 92 patients receiving either POSIMIR or placebo, and Part 2 consists of 296 patients receiving either POSIMIR or standard bupivacaine HCl. The primary efficacy endpoint for Part 2 is pain reduction on movement from 0-48 hours after surgery, with other key secondary endpoints including pain reduction on movement from 0-72 hours after surgery and 72-hour opioid use. In a previous clinical trial of 50 patients undergoing laparoscopic cholecystectomy, POSIMIR was compared with the active control bupivacaine HCl, against which POSIMIR demonstrated in a post hoc analysis an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.024) and for the first 2 days after surgery (p=0.0198), using the same statistical methodology specified for the current trial. There can be no assurance that the PERSIST trial will show similar results, or provide sufficient data for FDA approval.

About POSIMIR® (SABER-Bupivacaine)

POSIMIR is an investigational extended-release depot utilizing DURECT’s patented SABER technology intended to continuously deliver bupivacaine to the surgical site for 72 hours, to provide up to three days of continuous pain relief after surgery. POSIMIR is a drug candidate under development and has not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

About DURECT

DURECT is a biopharmaceutical company actively developing new therapeutics based on its Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 1 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, chronic metabolic diseases such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) and other liver diseases with both broad and orphan populations, and inflammatory skin conditions such as psoriasis. DURECT’s advanced oral, injectable, and transdermal 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 more information, please visit www.www.durect.com.

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. POSIMIR, DUR-928, and REMOXY 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.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential benefits and uses of our drug candidates, including the potential use of POSIMIR to treat post-surgical pain, the anticipated timing of the announcing of top-line results from the PERSIST trial, the potential milestone payments and royalties receivable from Sandoz, and the potential use of DUR-928 to treat NAFLD, NASH, other liver diseases, acute organ injury or inflammatory skin conditions such as psoriasis 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 PERSIST clinical trial of POSIMIR will take longer to analyze than anticipated or result in data that will not support a successful NDA resubmission or product approval, failure to achieve the performance milestones or commercial sales that trigger the referenced payments or royalties, possible adverse events associated with the use of POSIMIR, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR, our ability to manufacture, commercialize and obtain marketplace acceptance of POSIMIR, and avoid infringing patents held by other parties and secure and defend patents of our own, and risks related to our ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on May 10, 2017 under the heading "Risk Factors."

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-completes-enrollment-in-persist-phase-3-trial-for-posimir-300477758.html

SOURCE DURECT Corporation

Corporate: Matt Hogan, Chief Financial Officer, DURECT Corporation, 408-777-4936, matt.hogan@durect.com, Investor Contact: Matthew Duffy, LifeSci Advisors, 212-915-0685, matthew@lifesciadvisors.com