DURECT Announces Top-line Results from the PERSIST Phase 3 Trial of POSIMIR® (SABER®-Bupivacaine) Did Not Meet Primary Efficacy Endpoint

CUPERTINO, Calif., Oct. 19, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today reported that PERSIST, the Phase 3 clinical trial for POSIMIR® (SABER®-Bupivacaine), did not meet its primary efficacy endpoint of reduction in pain on movement over the first 48 hours after surgery as compared to standard bupivacaine HCl. While results trended in favor of POSIMIR versus the comparator, they did not achieve statistical significance. POSIMIR is an investigational drug candidate being developed for the treatment of post-surgical pain.

“We are very surprised and disappointed by these results, which we will be trying to understand more fully over the coming weeks,” said James E. Brown, President and CEO of DURECT Corporation. “We appreciate the efforts of the investigators and patients who participated in PERSIST, and we thank Sandoz for their support.”

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 the DURECT / Sandoz Collaboration

In May 2017, DURECT and Sandoz AG (“Sandoz“) entered into a license agreement to develop and market POSIMIR in the United States, and the agreement became effective in June 2017. DURECT retains commercialization rights in the rest of the world. Under terms of the agreement, Sandoz made an upfront payment of $20 million, with the potential for up to an additional $43 million in milestone payments based on successful development and regulatory milestones, and up to an additional $230 million in sales-based milestones. DURECT is responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval. DURECT also has certain manufacturing obligations under this agreement. Sandoz will have exclusive commercialization rights in the United States upon regulatory approval with sole funding responsibility for commercialization activities. Sandoz will pay the Company a tiered double-digit royalty on product sales for a defined period, after which the license granted to Sandoz shall convert to a non-exclusive, fully paid, royalty-free, irrevocable and perpetual license. Given the failure of PERSIST to achieve the primary endpoint, Sandoz has the right to terminate the agreement upon thirty (30) days prior written notice to DURECT.

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. In addition, for the assignment of certain patent rights, DURECT may receive a milestone payment from development and single digit sales based earn-out payments from sale of Indivior's RBP-7000 investigational drug for schizophrenia, for which Indivior recently submitted an NDA. 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 potential milestone payments and royalties receivable from Sandoz, the potential milestone payment and single-digit sales based earn-out payments receivable from Indivior, 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 Sandoz will terminate our agreement with them, that the results of the PERSIST trial lead us to terminate development of POSIMIR or increase the time and expense required to seek regulatory approval, and the risk that DUR-928 will not be found to be safe or effective in current or future clinical trials. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on August 5, 2017 under the heading "Risk Factors."

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