

DURECT and Sandoz have Signed a \$293 Million Development and Commercialization Agreement for POSIMIR[®] (SABER[®]-Bupivacaine) Covering the United States

NEWS PROVIDED BY
DURECT Corporation →
May 08, 2017, 07:00 ET

CUPERTINO, Calif., May 8, 2017 /PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced a development and commercialization agreement with Sandoz AG, a division of Novartis (NYSE: NVS), to develop and market in the United States DURECT's POSIMIR[®] (SABER[®]-Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery.

Sandoz is a global leader in driving sustainable access to high-quality healthcare. Sandoz's differentiated product portfolio includes a range of state-of-the-art technologies, formulations and devices. In the U.S., Sandoz Inc. has a dedicated hospital sales and marketing organization, with expertise and relationships, which will be employed to deliver POSIMIR to the market.

"We are delighted to collaborate with a company with the market presence and resources of Sandoz to commercialize POSIMIR in the United States," said James E. Brown, president and CEO of DURECT Corporation. "We believe that POSIMIR has the potential to become a cornerstone of multi-modal post-operative pain management. As a non-opioid local analgesic, we believe POSIMIR may be an important contributor to the ongoing efforts to reduce the use of opioid-based medications following surgery."

Under the terms of the agreement, Sandoz will make an upfront payment to DURECT of \$20 million, 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 will remain responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval. Closing of the transaction is anticipated to occur in the second quarter of 2017 and is contingent on completion of review under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.

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. DURECT is currently conducting PERSIST, a Phase 3 trial in patients undergoing laparoscopic cholecystectomy (gall bladder removal), comparing the effects of POSIMIR to bupivacaine HCl. DURECT expects to complete dosing patients in PERSIST in the third quarter of 2017 and to have top-line results soon thereafter. 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 and chronic metabolic diseases such as nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) and other liver diseases both broad and orphan. 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 three 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.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 enrollment of the PERSIST trial and the obtaining of top-line results from that trial, the potential milestone payments and royalties receivable from Sandoz, the potential use of DUR-928 to treat NASH, other liver diseases or acute organ injury, and potential markets for POSIMIR and DUR-928, 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 conduct 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-K filed on March 29, 2017 under the heading "Risk Factors."

SOURCE DURECT Corporation

Related Links

<http://www.durect.com>