DURECT's Collaboration with Sandoz Clears HSR Review and is Effective

CUPERTINO, Calif., June 19, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that the previously disclosed 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, has cleared review under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976 and has become effective.

Under the terms of the agreement, Sandoz has made 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 remains responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval.

"We are pleased to be collaborating on POSIMIR with Sandoz given their strong hospital presence in the U.S. and their strong record of commercializing innovative and value-added products that serve unmet medical needs," said James E. Brown, President and CEO of DURECT Corporation.

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.

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 second quarter of 2017 and to have top-line results in the fourth quarter of 2017. 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 enrollment of the PERSIST trial and the obtaining of top-line results from that 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 diseases 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 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-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/durects-collaboration-with-sandoz-clears-hsr-review-and-is-effective-300475310.html

SOURCE DURECT Corporation

Corporate Contact: 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