DURECT Announces POSIDUR™ (SABER®-Bupivacaine) Data Presentation at the International Anesthesia Research Society (IARS) Annual Meeting

CUPERTINO, CA, May 16, 2014 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) today announced that data for POSIDUR™ (SABER®-Bupivacaine), an investigational drug for administration into the surgical site to produce post-surgical analgesia, is being presented at the International Anesthetic Research Society (IARS) Annual Meeting. The meeting will be held on May 17-20 at the Fairmont Queen Elizabeth Hotel in Montreal.

“Bupivacaine is a widely used local anesthetic for post-op surgical pain, yet elevated concentrations of bupivacaine can cause cardiac adverse drug reactions,” said Tong J. Gan, M.D., MHS, professor of anesthesiology at Duke University School of Medicine. “SABER-bupivacaine is a depot formulation that controls the release of 660 mg of bupivacaine delivering 72 hours of post-operative pain relief. I will be sharing scientific data that indicates a clean cardiac safety profile in a clinical trial using Holter monitoring.”

“We are pleased to have this scientific data on POSIDUR presented at IARS 2014,” stated James E. Brown, President and CEO of DURECT Corporation. “At DURECT, we are committed to addressing the critical unmet patient need for a true 72 hour non-opioid post-op surgical pain anesthetic.”

Abstract information and authors for the poster that will be presented on Sunday, May 18, 2014 at 7:00-8:30 a.m.:

Presentation Title: Cardiac Safety of SABER®-Bupivacaine in Patients Undergoing Abdominal Surgery in the BESST Trial: An Assessment of Holter Monitoring Data from the BESST Trial
Authors: Dr. Tong J. Gan (Department of Anesthesiology, Duke University School of Medicine, Durham, NC), Dr. Anthony Fossa and Dr. Meijian Zhou (iCardiacTechnologies, Rochester, NY), Dr. David Ellis and Dr. Jaymin Shah (DURECT Corporation, Cupertino, CA), Dr. Craig Hartrick (William Beaumont Hospital, Troy, MI), Dr. Richard Watts (Department of Anaesthesia, The Queen Elizabeth Hospital, Woodville, South Australia, Australia)

About POSIDUR

POSIDUR is a post-operative pain relief depot that utilizes DURECT’s patented SABER® technology to deliver bupivacaine to provide up to three days of pain relief after surgery. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights. In February 2014, DURECT received a Complete Response Letter from the FDA for its new drug application (NDA) for POSIDUR. Based on its review, the FDA has determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA has indicated that additional clinical safety studies need to be conducted. DURECT is evaluating the issues described in the Complete Response Letter and plans to have further discussions with the FDA around them.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including Remoxy®, POSIDUR™, ELADUR®, and TRANSDUR®-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit http://www.www.durect.com/.

DURECT Forward-Looking Statement
The statements in this press release regarding POSIDUR, the potential benefits and uses of POSIDUR, our discussions with potential partners regarding licensing development and commercialization rights for POSIDUR, and our interactions with the FDA regarding approval of the POSIDUR NDA 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 risk that we will not be able to consummate any licensing transactions for development and commercialization of POSIDUR, the risk of adverse decisions by the FDA or other regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by the FDA or regulatory agencies, the risk that we may not be able to adequately address all of FDA's concerns regarding the POSIDUR NDA or there could be a delay in addressing such concerns, the potential that FDA may not grant regulatory approval of POSIDUR, the risk of potential adverse effects arising from additional testing or use of POSIDUR, and the potential that the data that we have generated or may generate may not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 2, 2014 under the heading "Risk Factors."

SOURCE: DURECT Corporation
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