



# DURECT Announces POSIDUR™ (SABER®-Bupivacaine) Data Presentations at the 39th Annual American Society of Regional Anesthetic and Pain Medicine Meeting

CUPERTINO, Calif., April 1, 2014 /PRNewswire/ — 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 39<sup>th</sup> Annual American Society of Regional Anesthetic and Pain Medicine Meeting. The meeting will be held on April 3-6 at the Sheraton Chicago Hotel and Towers in Chicago.

DURECT Corporation ([www.durect.com](http://www.durect.com)) is pioneering the development and commercialization of pharma

"We're pleased to have this presence at ASRA as part of our on-going effort to communicate to the medical community data that we have generated in our development program for POSIDUR," stated James E. Brown, President and CEO of DURECT Corporation.

Abstract information and authors for the following posters that will be presented on Saturday, April 5, 2014 at 9:30-11:00 a.m.:

**Presentation Title: Efficacy and Safety of SABER®-Bupivacaine Local Anesthetic in Open Hernia Repair**

Authors: Dr. Richard Watts (The Queen Elizabeth Hospital, Department of Anaesthesia, Woodville, South Australia, Australia), Dr. Dave Ellis and Dr. Neil Verity (DURECT Corporation, Cupertino, CA), Dr. Alex Yang (Xelay Acumen, Belmont, CA), Dr. Richard Turner (University of Tasmania School of Medicine, Hobart, Tasmania, Australia)

**Presentation Title: Treatment of Postoperative Pain in Shoulder Surgery with SABER®-Bupivacaine**

Authors: Dr. Anders Ekelund (Department of Orthopaedics, Capio St. Gorans Hospital, Stockholm, Sweden), Dr. Andrejs Peredistijs (Department of Orthopaedics, Clinic of Traumatology and Orthopaedics, Riga, Latvia), Dr. Josef Grohs (Department of Orthopaedics, Medical University of Vienna, Vienna, Austria), Dr. Dave Ellis and Dr. Neil Verity (DURECT Corporation, Cupertino, CA), Dr. Alex Yang (Xelay Acumen, Belmont, CA), Dr. Sten Rasmussen (Orthopaedic Surgery Research Unit, Medical Education, Aalborg University Hospital, Aalborg, Denmark)

**Presentation Title: Treatment of Postoperative Pain in Major Abdominal Surgery with SABER®-Bupivacaine: Results of the BESST Trial**

Authors: Dr. Tong J. Gan (Department of Anesthesiology, Duke University School of Medicine, Durham, NC), Dr. Harry Papaconstantinou (Department of Surgery, Scott and White Memorial Hospital and Clinic, Temple, TX), Dr. Marcel Durieux (Department of Anesthesiology, University of Virginia Health System, Charlottesville, VA), Dr. Neil Singla (Lotus Clinical Research, Inc., Arcadia, CA), Dr. Samir Johna (Department of Surgery, Kaiser Permanente, Fontana, CA), Dr. Dmitri Lissin, Dr. Neil Verity and Dr. Dave Ellis (DURECT Corporation, Cupertino, CA), Dr. Harold Minkowitz (Department of Anesthesiology, Memorial Hermann City Medical Center, Houston, TX)

**Presentation Title: Pharmacokinetic Characteristics of SABER®-Bupivacaine in Humans Demonstrate Sustained Drug Delivery for up to 72 Hours in a Variety of Surgical Models**

Authors: Dr. Jaymin Shah, Dr. Dave Ellis and Dr. Neil Verity (DURECT Corporation, Cupertino, CA)

## 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<sup>®</sup>, POSIDUR<sup>™</sup>, ELADUR<sup>®</sup>, and TRANSDUR<sup>®</sup>-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 [www.durect.com](http://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-K on February 28, 2014 under the heading "Risk Factors."

NOTE: POSIDUR<sup>™</sup>, SABER<sup>®</sup>, TRANSDUR<sup>®</sup>, and ELADUR<sup>™</sup> are trademarks of DURECT Corporation. Remoxy, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

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