



# DURECT Announces POSIDUR<sup>®</sup> (SABER<sup>®</sup>-Bupivacaine) Data Presentation at the American Society of Anesthesiologists Annual Meeting

CUPERTINO, Calif., Oct. 10, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that data for POSIDUR<sup>®</sup> (SABER<sup>®</sup>-Bupivacaine), an investigational drug for administration into the surgical site to produce post-surgical analgesia, is being presented at ANESTHESIOLOGY<sup>®</sup> 2014, the annual meeting of the American Society of Anesthesiologists (ASA). The meeting will be held October 11-15, 2014 at the Ernest N. Morial Convention Center in New Orleans.

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

“We are pleased to have this scientific data on POSIDUR presented at ASA,” stated James E. Brown, President and CEO of DURECT Corporation. “At DURECT, we are striving to address the critical unmet patient need for a non-opioid analgesic that provides pain relief for a full 3 days after surgery.”

Abstract information and authors for the poster that will be presented on Saturday, October 11, 2014 at 3:00-4:30 p.m.:

**Presentation Title: SABER<sup>®</sup>-Bupivacaine Reduced Pain Intensity for 72 Hours Following Abdominal Surgery Relative to Bupivacaine-HCl**

Authors: Dr. Tong J. Gan (Stony Brook University, Stony Brook, NY), Dr. Alex Yang (Xelay Acumen, Belmont, CA), Dr. Neil Verity and Dr. David Ellis (DURECT Corporation, Cupertino, CA)

Abstract information and authors for the posters that will be presented on Wednesday, October 15, 2014 at 10:00-11:30 a.m.:

**Presentation Title: SABER<sup>®</sup>-Bupivacaine Reduces Postoperative Pain Intensity and Opioid Use for 72 Hours in Soft-Tissue and Bony Surgeries**

Authors: Dr. John Moodie (Waikato Clinical Research and Braemer Hospital, Hamilton, New Zealand), Dr. Oliver Radke (Carl Gustav Carus an der Technischen University, Dresden, Germany), Dr. David 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: The PK Profile of SABER<sup>®</sup>-Bupivacaine in Humans Across Surgical Models Demonstrates Sustained 72-Hour Drug Delivery**

Authors: Dr. Jaymin Shah and Dr. Neil Verity (DURECT Corporation, Cupertino, CA), Dr. Alex Yang (Xelay Acumen, Belmont, CA)

**Presentation Title: SABER<sup>®</sup>-Bupivacaine Concurrently Reduces Postoperative Pain Intensity and Opioid Use for 72 Hours: Evaluation of CROPIRS Scores**

Authors: Dr. Richard W. Watts (The Queen Elizabeth Hospital, Woodville, Australia), Dr. Hinnerk F.W. Wulf (Universitätsklinikum Giessen, Marburg, Germany), Dr. Neil Verity (DURECT Corporation, Cupertino, CA), Dr. Alex Yang (Xelay Acumen, Belmont, CA), Dr. Anders Ekelund (Capio St Gorans Hospital, Stockholm, Sweden)

## About POSIDUR

POSIDUR is a post-operative pain relief depot that utilizes DURECT's patented SABER<sup>®</sup> 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 is having



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-Q filed with the Securities and Exchange Commission on August 8, 2014 under the heading "Risk Factors."

NOTE: POSIDUR<sup>®</sup>, SABER<sup>®</sup> and TRANSDUR<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.

Logo – <http://photos.prnewswire.com/prnh/20020717/DRRXLOGO>

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