DURECT Announces FDA Acceptance of New Drug Application (NDA) Submission for POSIDUR® (SABER®-Bupivacaine)

CUPERTINO, Calif., June 20, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that the New Drug Application (NDA) for the investigational product POSIDUR (SABER-Bupivacaine) has been accepted by the U.S. Food and Drug Administration (FDA) indicating that the application is sufficiently complete to permit a substantive review. POSIDUR is a post-operative pain relief depot that utilizes DURECT's patented SABER technology to deliver bupivacaine and is designed to provide up to three days of pain relief after surgery. DURECT submitted the NDA as a 505(b)(2) application. The Prescription Drug User Fee Act (PDUFA) goal date (the date the FDA expects to complete its review of the NDA) has been confirmed as February 12, 2014.

(Logo: http://photos.prnewswire.com/prnh/20020717/DRRXLOGO)

"We're extremely pleased that this NDA submission has been accepted for review and that our PDUFA date is now less than eight months away. If approved by the FDA, POSIDUR will provide a non-opioid alternative treatment option for post-surgical pain," James E. Brown, D.V.M., President and CEO of DURECT, stated. "Treating post-surgical pain with a true long-acting local anesthetic has the potential benefit of reducing the need for opioids and their associated systemic side effects that can prolong the time to recovery and result in extended hospital stays."

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.

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 www.www.durect.com.

DURECT Forward-Looking Statement
The statements in this press release regarding POSIDUR, possible approval of the NDA by the FDA, the potential benefits and uses of POSIDUR and discussions with potential partners regarding licensing 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 of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, the risk that the FDA will not complete review of the NDA by the PDUFA date, potential adverse effects arising from additional testing or use of POSIDUR, the potential that the data that we have generated may not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR, our potential inability to license rights to POSIDUR on commercially acceptable terms, or at all, and the risk of obtaining marketplace acceptance of POSIDUR, avoiding infringing patents held by other parties and securing and defending patents of our own, and managing and obtaining capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 3, 2013 under the heading "Risk Factors."

NOTE: POSIDUR™, SABER®, TRANSDUR®, and ELADUR™ 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.

SOURCE DURECT Corporation

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