DURECT Receives Complete Response Letter from FDA for POSIDUR™ (SABER®-Bupivacaine)

Company will Host Conference Call on February 13, 2014

CUPERTINO, Calif., Feb. 12, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter for POSIDUR™ (SABER®-Bupivacaine), an investigational drug for administration into the surgical site to produce post-surgical analgesia. 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.

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

“In the coming months, we intend to work with the FDA to gain more clarity on the next steps that would be required to address the issues cited in the Complete Response Letter,” stated James E. Brown, DVM, President and CEO of DURECT Corporation.

Conference Call and Webcast

A live audio webcast of a conference call will be broadcast over the internet at 8:30 a.m. Eastern Time on February 13 and is available by accessing DURECT’s homepage at www.www.durect.com and clicking “Investor Relations.” If you are unable to participate during the live webcast, the call will be archived on DURECT’s website under Audio Archive in the “Investor Relations” section.

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, the potential benefits and uses of POSIDUR, our on-going review and interactions with the FDA regarding approval of the POSIDUR NDA and the potential of resolving all outstanding regulatory concerns regarding POSIDUR 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 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 November 5,

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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