DURECT Provides Update on POSIDURâ?¢ Program

CUPERTINO, Calif., Nov. 11, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced that it has received meeting minutes from its face-to-face meeting with the FDA on September 23, 2014 regarding the POSIDURâ?¢ program. In the February 2014 Complete Response Letter (CRL), FDA indicated that multiple safety trials would be required to support a broad indication. DURECT inquired whether it would be possible to expedite approval by pursuing an initial indication of soft tissue post-surgical analgesia without conducting additional trials. FDA has indicated that in this scenario, it should be acceptable to conduct only one additional soft tissue clinical trial, the size of which is not yet defined, to generate the data required for product approval, including safety data for POSIDUR compared to a non-SABER containing comparator(s) and also product efficacy (to go along with the efficacy already demonstrated in our pivotal hernia trial).

“Based on the Complete Response Letter we anticipated that we would be required to do additional safety trials,” statedJames Brown, President and CEO of DURECT. “Over the coming months, we expect to have further communications with theFDA to refine the path forward.”

About POSIDUR

POSIDUR is an investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended 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, while at the same time we are preparing to be in a position to commercialize POSIDUR ourself in the U.S. in the event that we determine that is the preferred route of commercialization.

On February 12, 2014 we received a Complete Response Letter for POSIDUR from the FDA. Based on its review, theFDA 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 theFDA indicated that additional clinical safety studies need to be conducted.

About DURECT Corporation

DURECT is a specialty pharmaceuticalcompany developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXYÂ®, POSIDURâ?¢, ELADURÂ®, and TRANSDURÂ®-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 potential additional trials for POSIDUR, the potential resubmission of the NDA for POSIDUR to the FDA, the potential regulatory approval of POSIDUR by the FDA, potential licensing transactions for POSIDUR, the potential benefits and uses of POSIDUR, and the potential uses and benefits of DURECT's other product candidates 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 additional trials and studies will not have satisfactory outcomes, the risk of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of POSIDUR, the potential that data submitted in response to the complete response letter will not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR, 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 for the quarter ending September 30, 2014, filed with the Securities and Exchange Commission on November 4, 2014, under the heading "Risk Factors."

NOTE: POSIDURâ?¢, SABERÂ® and TRANSDURÂ® 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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