DURECT Announces Participation in Bay Area Prescription Drug Abuse Summit Meeting

CUPERTINO, Calif., May 7, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that James E. Brown, President and CEO of DURECT Corporation, will be an industry speaker at the Bay Area Prescription Drug Abuse Summit on May 7, 2014 in San Francisco. The summit is an effort to bring together senior policymakers, medical professionals, educators, local, state and federal law enforcement and the community to seek solutions to this problem and to raise awareness of the issue.

“We’re pleased to present at this forum given our significant involvement in developing products that may address the widespread abuse and misuse of opioids, both through abuse-deterrent formulations and through a novel extended release formulation of a local anesthetic which may reduce the need for opioids after surgery,” stated James E. Brown, President and CEO of DURECT Corporation.

About REMOXY (oxycodone) Extended-Release Capsules CII.

REMOXY is an investigational drug based on DURECT’s ORADUR® proprietary technology and under development by Pfizer. It is a unique long acting oral formulation of oxycodone intended to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. REMOXY is designed to discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse. Pfizer has efforts underway to resolve the issues raised in the Complete Response Letter for REMOXY, which primarily relate to manufacturing. Following guidance received from the FDA in 2013, Pfizer announced that they will proceed with the additional clinical studies and other actions required to address the Complete Response Letter received in June 2011. As previously disclosed, the complete response submission is not expected to occur prior to mid-2015.

About POSIDUR

POSIDUR is our investigational 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. We are evaluating the issues described in the Complete Response Letter and plan to have further discussions with the FDA around them.

Other ORADUR-based Opioids. DURECT has licensed three other ORADUR-based opioids (hydrocodone, hydromorphone and oxymorphone) to Pain Therapeutics. Phase I clinical trials have been conducted for ORADUR-hydrocodone and ORADUR-hydromorphone, and an Investigational New Drug (IND) application has been accepted by the FDA for ORADUR-oxymorphone. During the first quarter of 2014, we conducted research and development activities on these programs under approved workplans with Pain Therapeutics.

ORADUR-ADHD Program. In 2013, DURECT selected a lead formulation for the lead program in our ORADUR-ADHD (Attention Deficit Hyperactivity Disorder) program, ORADUR-Methylphenidate. This formulation was chosen based on its potential for rapid onset of action, long duration with once-a-day dosing and target pharmacokinetic profile as demonstrated in a Phase 1 trial. In addition, this product candidate utilizes a small capsule size relative to the leading existing long acting products on the market and incorporates our ORADUR anti-tampering technology. Our licensee, Orient Pharma, has met with the Taiwan Food and Drug Administration (TFDA) to discuss the Phase 3 program in that market and is developing its plans for further development in the defined Asian and South Pacific countries to which it has rights from us. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan, and are engaged in licensing discussions with other companies.

About DURECT Corporation

DURECT is a specialty pharmaceuticalcompany 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 the Bay Area Prescription Drug Abuse Summit, potential regulatory meetings and discussions and submissions for REMOXY and POSIDUR, potential FDA approval of REMOXY, POSIDUR, or any of our other product candidates, anticipated studies and clinical trials (including timing and results) for REMOXY, POSIDUR and our other drug candidates, the potential benefits and uses of our drug candidates, collaborations with third parties and potential business development, licensing and commercialization activities 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 Pfizer will discontinue development of REMOXY, the risk of adverse decisions by regulatory agencies, including rejection of meeting requests, requests for additional information or product non-approval or non-acceptance of our POSIDUR or other NDA submissions, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of our drug candidates, the potential failure of clinical trials to meet their intended endpoints, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and risks related to our (and our third party collaborators where applicable) ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of product candidates, manufacture and commercialize product candidates, obtain marketplace acceptance of product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ending March 31, 2014 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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