DURECT Announces Intent to Submit NDA for POSIDUR™ for Post-Operative Analgesia

CUPERTINO, Calif., Aug. 6, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has completed its pre-NDA communications with the United States Food and Drug Administration (FDA) regarding POSIDUR™ (SABER®-Bupivacaine). Through this process, DURECT has received guidance and thoughtful comments from the FDA covering various chemistry, manufacturing, non-clinical, clinical pharmacology, clinical, statistical and product labeling topics based on our pre-NDA meeting questions. We have sent to the FDA meeting minutes and are awaiting their final concurrence on those minutes. With the input we have received from the FDA, DURECT intends to prepare and submit a new drug application (NDA) under 505(b) with the FDA in late 2012 or early 2013. POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER technology to deliver bupivacaine and is designed to provide up to three days of pain relief after surgery.

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

“Following our recent interactions with the FDA, our team is now focusing on finalizing the NDA for submission to the FDA based on all of the data generated throughout our POSIDUR development program,” stated James Brown, President and CEO of DURECT. “We believe that POSIDUR may offer benefit to patients by providing local analgesia for up to three days after surgery.”

About POSIDUR™

POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER® technology to deliver bupivacaine and is designed to provide up to three days of pain relief after surgery. In the U.S., POSIDUR is covered by two patent families, which include granted patents expiring in at least 2015 and 2025, respectively. In Europe, POSIDUR is covered by two granted patents expiring in 2016 and 2025, respectively, plus any eligible patent term extensions. We currently hold worldwide commercialization rights to POSIDUR.

About SABER® Technology

The SABER technology is a patented extended-release technology that can be formulated for systemic or local administration of active agents via the parenteral or oral route. We believe that our SABER system can provide the basis for the development of state-of-the-art biodegradable, extended-release injectables. The SABER system uses a high-viscosity base component, such as sucrose acetate isobutyrate (SAIB), to provide extended release of a drug. When the high viscosity SAIB is formulated with drug, biocompatible excipients and other additives, the resulting formulation is liquid enough to administer easily with standard syringes. After administration of a SABER formulation, excipients diffuse away, leaving a viscous depot. Depending on how it is formulated, the SABER system can successfully deliver therapeutic levels of a wide spectrum of drugs from one day to three months from a single administration.

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 DURECT‘s intention to prepare and submit a new drug application with the FDA for POSIDUR in late 2012 or early 2013, and the potential benefits and uses of 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 that the NDA submission may not occur in late 2012 or early 2013 as intended, the risk that if submitted the FDA may not accept the NDA for review and, if reviewed by the FDA, will not be approved by the FDA, requests for additional information or analysis by the FDA, including additional clinical trials, delays and additional costs

due to requirements imposed by the FDA, potential adverse effects arising from the testing or use of POSIDUR, failure to manufacture, and commercialize or obtain marketplace acceptance of POSIDUR, the risk of patent validity being challenged and not upheld, and the risk of infringing patents held by other parties. Further information regarding these and other risks is included in DURECT's Form 10-Q on May 4, 2012 under the heading "Risk Factors."

NOTE: POSIDUR™, SABER®, ORADUR®, TRANSDUR®, and ELADUR™ are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. 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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