DURECT Announces ELADUR(R) (TRANSDUR(R)-Bupivacaine) Phase II Study Results in Chronic Low Back Pain

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DURECT Corporation (Nasdaq: DRRX) announced today top-line results from a Phase II clinical trial in chronic low back pain for ELADUR(R) (TRANSDUR(R)-Bupivacaine), DURECT's proprietary investigational transdermal bupivacaine pain patch. This study was conducted by DURECT's collaborator, King Pharmaceuticals, which is now owned by Pfizer (NYSE: PFE). In this study of 263 patients suffering from chronic low back pain, the primary efficacy endpoint of demonstrating a positive treatment difference for the mean change in pain intensity scores from baseline to the mean of weeks 11 and 12 between ELADUR as compared to placebo was not met. Complete data analysis is on-going.

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

ELADUR is an investigational transdermal drug patch intended to deliver bupivacaine for up to 3 days from a single application. Bupivacaine, the active agent in ELADUR, is a potent, FDA-approved long-acting local anesthetic used in regional anesthesia for local tissue infiltration, nerve block, and epidural and intrathecal anesthesia. ELADUR demonstrated a positive efficacy trend in a Phase 2a study for post-herpetic neuralgia (PHN); a poster describing this study was presented at the 27th Annual Scientific Meeting of the American Pain Society on May 8, 2008 and is accessible on DURECT's website (http://www.www.durect.com/wt/durect/page_name/Publications).

"Demonstrating efficacy against placebo in a chronic low back pain trial is challenging for any topical locally-acting product," stated James E. Brown, DVM, President and CEO of DURECT. "We and Pfizer are continuing to analyze this most recent study and will work together to determine next steps."

About the DURECT / Pfizer Collaboration

In October 2008, DURECT signed a development and license agreement with Alpharma Ireland Limited (subsequently acquired by King Pharmaceuticals in December 2008 and King was subsequently acquired in February 2011 by Pfizer) whereby Alpharma was granted the exclusive worldwide rights to develop and commercialize ELADUR, an investigational bupivacaine patch. Under the terms of the agreement, Alpharma paid DURECT an upfront license fee of $20 million, with possible additional payments of up to $93 million upon the achievement of predefined development and regulatory milestones spread over multiple clinical indications and geographical territories as well as possible additional payments of up to $150 million in sales-based milestones. If ELADUR is commercialized, DURECT would also receive royalties on product sales. Pfizer controls and funds any further development of the program.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(R), and TRANSDUR(R)-Sufentanil. DURECT's proprietaryoral, transdermal and injectable depot delivery technologies may 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.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(R), and ELADUR(R) 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.

DURECT Forward-Looking Statement

The statements in this press release regarding ELADUR, including its potential uses and benefits, future development activities and the potential milestone payments and royalties receivable from our agreement with Pfizer (Alpharma) 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 possible failure to demonstrate efficacy in future clinical trials, potential side effects or adverse events observed during clinical trials, possible delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of ELADUR, possible commercial challenges including competition from other products, difficulty in gaining reimbursement and generic competition, and the possible impact of these factors on Pfizer's interest in developing or commercializing ELADUR. Further information regarding these and other risks is included in DURECT's Form 10-K filed on March 3, 2011 under the heading "Risk Factors."

SOURCE DURECT Corporation