



# **DURECT Corporation Announces Commencement of Phase IIb ELADUR(TM) (TRANSDUR(TM)-Bupivacaine) Clinical Trial by King Pharmaceuticals**

CUPERTINO, Calif., April 7, 2010 /PRNewswire via COMTEX/ –DURECT Corporation (Nasdaq: DRRX) announced today that its licensee, King Pharmaceuticals (NYSE: KG), has begun a Phase IIb clinical trial to evaluate ELADUR(TM) (TRANSDUR(TM)-Bupivacaine) for the treatment of chronic low back pain. ELADUR is an investigational transdermal drug patch intended to deliver bupivacaine for up to 3 days from a single application. This Phase IIb trial is a 12-week, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of ELADUR in patients with chronic low back pain. King expects to enroll approximately 260 patients in the study.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO>)

"We're pleased that King is developing ELADUR for chronic low back pain, a clinical indication for which currently marketed anesthetic patches are not approved," stated James E. Brown, President and CEO of DURECT Corporation. "If approved for chronic low back pain, we believe that this novel bupivacaine patch has the potential to compete strongly in the large market for topical pain products given its patient friendly design and extended duration of therapeutic use."

## **About ELADUR**

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.

## **About the DURECT / King Pharmaceuticals Collaboration**

In October 2008, DURECT signed a development and license agreement with Alpharma Ireland Limited (subsequently acquired by King Pharmaceuticals in December 2008) 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. Alpharma controls and funds further development of the program.

## **About DURECT Corporation**

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-Sufentanil. DURECT's proprietary oral, 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.durect.com](http://www.durect.com).

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(TM), and ELADUR(TM) 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 the ELADUR Phase IIb trial, including anticipated enrollment, and potential regulatory approval, uses and benefits of ELADUR and the potential milestone payments and royalties receivable from our agreement with 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, King's ability to enroll patients in the ELADUR trial in a timely manner, King's reliance on third-party contract research organizations for the conduct of the ELADUR Phase IIb trial, potential side effects or adverse events observed during the ELADUR Phase IIb trial or in other clinical trials of ELADUR, whether ELADUR will meet the endpoints set forth in the Phase IIb trial or in other clinical trials, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of ELADUR, our ability to complete the design, development, and manufacturing process development of ELADUR, and to manufacture, commercialize and obtain marketplace acceptance of ELADUR, and avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-K filed on March 4, 2010 under the heading "Risk Factors."

SOURCE DURECT Corporation