DURECT Reports Positive Phase IIb Data from POSIDUR(TM) Clinical Program

CUPERTINO, Calif., Dec 17, 2009 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today positive results from a 60 patient Phase IIb clinical trial of POSIDUR(TM), a proprietary product under development for the treatment of post-surgical pain. Top line results from this study of patients undergoing arthroscopic shoulder surgery showed a consistent reduction of pain scores (as measured by mean pain intensity on movement AUC, time normalized under the curve, during the period 0 to 72 hours post-surgery) in parallel with a reduction of opioid use (as measured by the amount of opioids taken in the three days post-surgery) in favor of POSIDUR versus placebo. These reductions were not statistically significant given the size of the study. In addition, there was a comparable safety profile between the two groups in this study and POSIDUR appeared well tolerated.

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

“We are pleased that this study provides a consistent signal of the analgesic effectiveness of POSIDUR in an orthopedic surgical model,” stated James E. Brown, President and CEO of DURECT Corporation. “We look forward to commencing enrollment of the U.S. Phase III program in the first quarter of 2010.”

The POSIDUR Phase IIb clinical trial was a double blind, multi-center, placebo controlled, parallel group trial in patients undergoing arthroscopic shoulder surgery. Eligible patients were randomly assigned to one of two treatment groups prior to surgery (SABER(TM)-Bupivicaine (POSIDUR) or SABER-Placebo). Supplemental rescue analgesia for post-operative shoulder pain in both treatment groups was provided if needed. The study was conducted at sites in Australia and New Zealand.

POSIDUR

POSIDUR is a long-acting local anesthetic under development by DURECT and Nycomed for the treatment of post-surgical pain. It is intended to be administered during surgery, where it continuously releases therapeutic levels of bupivacaine in a controlled fashion, providing up to 72 hours of uninterrupted local analgesia. POSIDUR’s performance is due to DURECT’s patented SABER(TM) delivery system, an injectable, biodegradable drug delivery technology.

About the DURECT / NYCOMED Collaboration

In November 2006, DURECT signed a collaboration agreement with Nycomed, a privately-held European pharmaceutical company headquartered in Switzerland, whereby the companies are jointly developing DURECT’s POSIDUR post-operative pain relief depot for the U.S. and the European Union (E.U.). The two parties are jointly directing and equally funding a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. DURECT has licensed Nycomed the exclusive commercialization rights to POSIDUR in the E.U. and select other countries. In addition, under the agreement, DURECT will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. DURECT retains full ownership of POSIDUR in the U.S., Canada, Asia and other countries.

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 http://www.www.durect.com/.

DURECT Forward-Looking Statement

The statements in this press release regarding the potential uses and benefits of POSIDUR and our intended activities relating to POSIDUR, including our plan to commence enrollment of the U.S. Phase III program in the first quarter of 2010, 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, DURECT's and Nycomed's difficulty or failure to obtain approvals from regulatory agencies with respect to its clinical trials and other development activities, the companies potential difficulty or failure to agree upon the development plan and funding of the joint U.S. and E.U. development program, or their respective abilities to design, enroll, conduct and complete clinical trials, failure of such clinical trials to produce intended results, possible adverse events associated with the use of POSIDUR, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIDUR, our ability to consummate collaborative agreements relating to POSIDUR, our ability to complete the design, development, and manufacturing process development of POSIDUR, and to manufacture, commercialize and obtain marketplace acceptance of POSIDUR, 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-Q filed on November 2, 2009 under the heading "Risk Factors."

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