DURECT Completes Enrollment in Pivotal U.S. Phase III Trial for POSIDURÂ® (BESST)

CUPERTINO, Calif., Sept. 6, 2011 /PRNewswire via COMTEX/ —

DURECT Corporation (Nasdaq: DRRX) announced today the dosing of the last patient in the U.S. pivotal Phase III clinical study for POSIDURÂ® known as BESST (Bupivacaine Effectiveness and Safety in SABER trial). POSIDUR is a post-operative pain relief depot that utilizes DURECT's patented SABER(TM) technology to deliver bupivacaine to provide up to three days of pain relief after surgery. DURECT expects to report top-line data from the BESST trial in the fourth quarter of 2011 and, if the data are positive, to submit the New Drug Application in the first half of 2012.

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

"We believe that POSIDUR has the potential to play a major role in treating post-surgical pain, reducing the need for systemic narcotics and associated side effects, as well as costs associated with extended hospital stays," statedJames E. Brown, President and CEO.

"We are encouraged by this important development milestone for POSIDUR, an innovative product candidate which may represent a significant step-forward in the management of acute pain for patients following surgical procedures. Hospira is committed to bringing POSIDUR to market rapidly following FDA review and approval," addedAndrew Robbins, Vice President, corporate development at Hospira, Inc.POSIDUR is licensed to Hospira (NYSE: HSP) for commercialization in the U.S. andCanada.

About the Design of BESST

BESST is an international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, effectiveness, and pharmacokinetics of POSIDUR in 305 patients undergoing a variety of general abdominal surgical procedures. Eligible patients were randomly assigned to one of three cohorts:

Cohort 1: An active comparator cohort in which 48 patients were randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparotomy.

Cohort 2: An active comparator cohort in which 50 patients were randomized to receive either POSIDUR 5.0 mL or commercially available Bupivacaine HCl solution after laparoscopic cholecystectomy.

Cohort 3: A double blind, placebo controlled cohort in which 207 patients were randomized to receive either POSIDUR 5.0 mL or SABER-Placebo after laparoscopically-assisted colectomy.

Efficacy evaluation in the BESST trial will encompass a number of parameters. The two co-primary efficacy endpoints for Cohort 3 are mean pain intensity on movement (normalized) Area Under the Curve (AUC) during the period 0-72 hours post-dose and mean total morphine equivalent opioid dose for supplemental analgesia during the period 0-72 hours post-dose. The purpose of Cohorts 1 and 2 is to give additional experience with the use of POSIDUR in a broader group of surgeries and patients; these smaller cohorts were not intended to provide statistical significance with respect to efficacy. InApril 2010, DURECT had a FDA interaction which increased our confidence that the BESST design and overall NDA strategy, subject to data review from the entire POSIDUR development program, addresses the FDA's comments provided during past interactions regarding safety and evaluation of a diverse patient population that is likely to be exposed to the marketed product.

About POSIDUR

POSIDUR is a post-operative pain relief depot that utilizes DURECT's patented SABER(TM) technology to deliver bupivacaine to provide up to three days of pain relief after surgery. POSIDUR is licensed to Hospira for commercialization in the U.S. andCanada, and to Nycomed for commercialization in Europe and other defined countries. DURECT has retained commercialization rights in Japan and all other countries not subject to the Nycomed and Hospira licenses.

About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXYÂ®, POSIDUR(TM), ELADURÂ®, and TRANSDURÂ®-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 anticipated reporting of top-line data from BESST, submission of a New Drug Application for POSIDUR, bringing of POSIDUR to market, 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 of adverse decisions by regulatory agencies, including product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of POSIDUR, the potential failure of BESST and our other clinical trials to meet their intended endpoints, the potential that the data that we have generated may not be deemed sufficient by FDA or other regulatory agencies to support regulatory approval of POSIDUR, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and DURECT's (and that of its third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to its development activities and products, or ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, manufacture and commercialize the referenced product candidates, obtain marketplace acceptance of the referenced product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund its growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on August 5, 2011 under the heading "Risk Factors."

SOURCE DURECT Corporation