DURECT Initiates U.S. Pivotal Phase III POSIDUR(TM) Clinical Trial

BESST (Bupivacaine Effectiveness and Safety in SABER(TM) Trial) Targets Post-Surgical Pain

CUPERTINO, Calif., Jan 19, 2010 /PRNewswire via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that it has begun dosing patients in its U.S. pivotal Phase III clinical trial to evaluate POSIDUR(TM) (SABER(TM)-Bupivacaine), an investigational drug, for the treatment of post-surgical pain. The pivotal trial, referred to as BESST (Bupivacaine Effectiveness and Safety in SABER Trial), is an international, multi-center, randomized, double-blind, controlled trial evaluating the safety, efficacy, effectiveness, and pharmacokinetics of POSIDUR in patients undergoing general surgical procedures. We expect to enroll approximately 300 patients at approximately 20 clinical trial sites in the study.
(Logo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO)

“Initiation of our Phase III BESST program represents a significant milestone for DURECT,” stated James E. Brown, President and CEO of DURECT Corporation. “We believe that POSIDUR, if approved, could improve the treatment of patients’ post-surgical pain and reduce the use of opioids in this setting.”

“BESST was designed based on feedback from the FDA as well as input from expert consultants and key opinion leaders,” stated Joe Stauffer, Chief Medical Officer of DURECT Corporation. “We anticipate completing enrollment in the first half of 2011.”

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 approximately 300 patients undergoing a variety of general abdominal surgical procedures. Eligible patients will be randomly assigned to one of three cohorts:

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

Cohort 2: An active comparator cohort in which patients are 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 patients are 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 will be 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. An adaptive feature of BESST allows for upsizing of the patient sample size in Cohort 3 based on pooled and blinded data. The purpose of Cohorts 1 and 2 is to give us additional experience with the use of POSIDUR in a broader group of surgeries and patients.

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 DURECT has licensed Nycomed the exclusive commercialization rights to POSIDUR in the European Union (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.

The agreement currently provides for the two parties to jointly direct and equally fund a development program for POSIDUR intended to secure regulatory approval in both the U.S. and the E.U. However, DURECT and Nycomed are currently negotiating an amendment to the agreement intended to give DURECT and Nycomed each the sole, final decision making authority and financial responsibility for the remaining clinical programs for the U.S. in the case of DURECT and the E.U. in the case of Nycomed. This proposed amendment reflects the divergence between the clinical development programs required for regulatory approval as between the U.S. and E.U. while preserving the close cooperation and sharing of data for the mutual benefit of both parties. As the parties are negotiating this proposed amendment, DURECT is solely responsible for funding BESST.

Conference Call

A live audio webcast of a conference call to discuss BESST will be broadcast over the internet at 11:00 a.m. Eastern Time on January 19 and is available by accessing DURECT's homepage at www.www.durect.com and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

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 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.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 BESST trial, potential uses and benefits of POSIDUR, and our agreement with Nycomed regarding future funding arrangements for the development program for 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, DURECT's ability to enroll patients in the BESST trial in a timely manner, DURECT's reliance on third-party contract research organizations for the conduct of the BESST trial, potential side effects or adverse events observed during the BESST trial or in other clinical trials of POSIDUR, whether POSIDUR will meet the endpoints set forth in the BESST trial or in other clinical trials, whether DURECT will reach agreement with Nycomed regarding financial arrangements for the development program for POSIDUR, the companies potential difficulty or failure to agree upon the development plan and funding of the joint U.S. and E.U. development program, 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."

SOURCE DURECT Corporation