DURECT Reports Data From European Phase IIb Hysterectomy Study of POSIDUR(TM) (SABER(TM)-Bupivacaine)

CUPERTINO, Calif., June 16, 2010 /PRNewswire via COMTEX/ –DURECT Corporation (Nasdaq: DRRX) announced today results from a European Phase IIb hysterectomy clinical trial conducted by Nycomed of POSIDUR(TM) (also known as SABER(TM)-bupivacaine or Optesia(TM) in the E.U.), a proprietary product under development for the treatment of post-surgical pain.

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This hysterectomy trial is part of Nycomed's clinical development program for Europe for POSIDUR. In this study, 115 patients were randomly assigned to one of three treatment groups prior to undergoing open hysterectomy surgery: POSIDUR at a dose of 5 mL, an active comparator (commercially available bupivacaine HCI solution) or SABER-Placebo (SABER vehicle without drug). All patients were given a background pain treatment consisting of a daily dose of two or four grams (depending on the patient's weight) of paracetamol (acetaminophen). In addition, each patient was provided supplemental opioid rescue medication, if needed.

With respect to efficacy, the primary endpoints of the study were to show (1) non-inferiority of POSIDUR to SABER-Placebo (with all groups taking the background and supplemental pain treatment as described above) in terms of pain intensity on movement area under the curve (AUC) during the period 1-72 hours post-surgery, and (2) superiority of POSIDUR against SABER-Placebo in the total use of opioid rescue analgesia 0-72 hours post-surgery. Results from this study show that the first primary endpoint was met. With respect to the second primary efficacy endpoint, no statistically significant difference was shown in opioid use between the POSIDUR and SABER-Placebo groups. Secondary comparisons were performed towards the active comparator group with similar results. In this study, patients in all treatment groups only took a meaningful amount of opioids during a shorter period of time after surgery than was expected.

In this study, there were no indications of systemic safety issues. The plasma concentration profiles were consistent with previous studies, confirming the sustained release profile of the product. Local observations (most commonly coded as post procedural haematomas) at the surgical site were observed with frequency in the POSIDUR and SABER-Placebo groups and not observed in the active comparator group. These events were temporary and resolved without treatment.

"The data from this study further supports the CNS and cardiovascular safety profile of POSIDUR in another surgical model, but when few opioids are taken, it is difficult to show a reduction in opioid use," stated James E. Brown, President and CEO of DURECT Corporation. "We are currently enrolling in BESST, our U.S. pivotal Phase III study and Nycomed continues to enroll in a Phase IIb study in Europe in shoulder surgery. In addition, we had a recent 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."

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 international pharmaceutical company headquartered in Zurich, Switzerland, whereby DURECT has licensed Nycomed the exclusive commercialization rights to

POSIDUR in the European Union (E.U.) and selected other countries. DURECT is eligible to receive future milestone payments from Nycomed of up to $181 million upon achievement of defined development, regulatory and sales milestones. In addition, DURECT will manufacture and supply the product to Nycomed for commercial sale in the territory licensed to Nycomed. Nycomed will pay DURECT blended royalties on sales in the defined territory of 15-40% depending on annual sales.

About the DURECT / Hospira Collaboration

In June 2010, DURECT signed a collaboration agreement with Hospira, Inc. whereby DURECT has licensed Hospira the exclusive development and commercialization rights to POSIDUR in the United States and Canada. DURECT will receive an upfront payment of $27.5 million, with the potential for up to an additional $185 million in performance based milestone payments based on the successful development, approval and commercialization of POSIDUR. For the U.S. and Canada, the two companies will jointly direct and equally fund the remaining development costs, while Hospira will have exclusive commercialization rights with sole funding responsibility. In addition, Hospira will pay DURECT a royalty on product sales. DURECT retains full ownership of POSIDUR in Japan and selected other territories not explicitly granted to Nycomed or Hospira.

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 potential uses and benefits of POSIDUR, indications of clinical efficacy and safety of POSIDUR, the design of BESST and overall NDA strategy and possible royalties and milestone payments receivable from our collaborations with Nycomed and Hospira 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, our and our collaborators' difficulty or failure to obtain approvals from regulatory agencies with respect to clinical trials and other development activities, or design, enroll, conduct and complete clinical trials, failure of such clinical trials to produce intended results or to confirm results from earlier clinical trials, 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 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 May 10, 2010 under the heading "Risk Factors."

SOURCE DURECT Corporation