DURECT Reports Data From European Phase IIb Shoulder Study of POSIDUR(TM) (SABER(TM)-Bupivacaine) and Amendment of the Nycomed Agreement

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DURECT Corporation (Nasdaq: DRRX) announced today results from a European Phase IIb shoulder 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, and the amendment of the Company's collaboration agreement with Nycomed.

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

This shoulder trial is part of Nycomed's clinical development program for Europe for POSIDUR. In this study, 107 patients were randomly assigned to one of three treatment groups prior to undergoing elective arthroscopic shoulder 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.

The primary efficacy endpoints of this Phase IIb study were to demonstrate: (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. Top-line results from this study demonstrate that the POSIDUR group experienced a statistically significant reduction in pain intensity versus SABER-Placebo. The results of the pre-specified primary analysis indicated a clear clinically relevant trend in opioid sparing for POSIDUR compared to SABER-placebo and the pre-specified sensitivity analysis showed a statistically significant difference in opioid sparing in favor of POSIDUR. No statistical differences were found when POSIDUR was compared to the active comparator arm.

Overall, there was a comparable safety profile between the three groups in this study and POSIDUR appeared well tolerated.

Nycomed is currently finalizing the Phase IIb shoulder study clinical trial report and will be evaluating the E.U. program for POSIDUR pending a review of data from the U.S. Phase III trial (BESST) which involves three abdominal surgical models. Until results are received from BESST, the parties have amended their agreement such that DURECT will have full control and financial responsibility for non-clinical and CMC activities which had been previously jointly controlled and funded by DURECT and Nycomed. If Nycomed elects to continue European development of POSIDUR after evaluation of BESST data, under the terms of the amendment, DURECT and Nycomed would resume joint control and financial responsibility of the non-clinical and CMC activities for the EU and the U.S.

"We are pleased to have data from an orthopedic model which showed that patients treated with POSIDUR had better pain control and consumed fewer opioids compared with patients on placebo while also showing a good safety profile," statedJames E. Brown, President and CEO of DURECT. "The purpose of the amendment is to provide Nycomed with the opportunity to review the European program with BESST data in hand while in the meantime we and Hospira (our collaborator in the U.S. andCanada) continue to drive forward and control the CMC and non-clinical development activities in anticipation of preparing our U.S. NDA submission. We are currently enrolling in BESST, our U.S. pivotal Phase III study and anticipate completing enrollment of that study in the first half of 2011."

POSIDUR

POSIDUR is a long-acting local anesthetic under development by DURECT and Hospira (for the U.S. andCanada) and by DURECT and Nycomed (for Europe and other defined territories) 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 Switzerland, whereby DURECT has licensed Nycomed the exclusive commercialization rights to POSIDUR in the European Union (E.U.) and select other countries. This agreement was subsequently amended inFebruary 2010 and in February 2011.

About DURECT Corporation

DURECT is a 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(R)-Sufentanil. DURECT's proprietaryoral, 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(R), 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 US 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 and our and our partners intended activities relating to POSIDUR, including our expectation of completing enrollment of the U.S. Phase III program in the first half of 2011 and the potential for Nycomed to continue funding development activities 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, our ability to enroll the BESST trial in a timely basis, our and Hospira's ability to conduct and complete on-going clinical trials or to design and enroll additional clinical trials, if any, required for regulatory approval, failure of such clinical trials to produce intended results, Nycomed's evaluation of the results of the BESST trial and their decision whether to continue development and funding of POSIDUR, which is in their sole discretion, 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 November 4, 2010 under the heading "Risk Factors.

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