DURECT and Nycomed Amend POSIDUR(TM) License Agreement to Separate Funding and Control of U.S. and E.U. Clinical Programs and to Expand Territory

CUPERTINO, Calif., Feb 22, 2010 /PRNewswire via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today that Nycomed and DURECT have amended the Development and License Agreement entered into between the parties in 2006 covering the development and commercialization of POSIDUR(TM) (also known as SABER(TM)-Bupivacaine or OPTESIA(TM)), an investigational drug for the treatment of post-surgical pain.

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

The amendment provides DURECT with final decision-making authority over clinical trials intended for the U.S. registration of POSIDUR and Nycomed with decision-making authority over clinical trials for the E.U. and other countries licensed to it. DURECT will have funding responsibility for all current and future clinical trials intended for U.S. registration of POSIDUR and, commencing April 1, 2010, Nycomed will have sole funding responsibility for all clinical trials intended for E.U. registration of OPTESIA (Nycomed's brand name for this drug candidate). The parties are not altering the final decision making authority and financial responsibility for the remainder of the development activities, such as the non-clinical and CMC activities, which will continue to be jointly managed and funded by DURECT and Nycomed. The amendment further expands the territories licensed to Nycomed to include China, Hong Kong, Malaysia, Philippines, Singapore, Taiwan, Vietnam, Thailand, Indonesia, India and Venezuela. DURECT retains full ownership of POSIDUR in the U.S., Canada, Japan and other territories not granted to Nycomed.

"Nycomed has been a strong partner for DURECT since the inception of our relationship, and the early portions of the U.S. and E.U. development programs have benefited from the joint guidance and co-funding by the parties. However, at this later stage of development, given the divergence between the clinical development programs required for regulatory approval as between the U.S. and E.U., and our aspirations to partner POSIDUR in the U.S., this amendment provides greater flexibility for both parties in their respective territories while at the same time preserving the close cooperation and sharing of data for our mutual benefit," stated James E. Brown, President and CEO of DURECT Corporation. "We also believe that Nycomed will diligently exploit the additional countries granted to them, from which we will benefit under the same favorable commercial terms as in our original agreement."

DURECT recently commenced BESST (Bupivacaine Effectiveness and Safety in SABER(TM) Trial), which is intended to be the pivotal Phase III clinical trial in the U.S. In Europe, Nycomed is currently conducting two Phase IIb clinical trials (in hysterectomy and in shoulder surgery) with OPTESIA(TM).

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. 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. DURECT retains full ownership of POSIDUR in the U.S., Canada, Japan and other territories not granted to Nycomed.

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 http://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 our intention to license the rights to POSIDUR in the U.S., the potential uses and benefits of POSIDUR and our agreement with Nycomed for POSIDUR, including the potential milestone payments and royalties that may be received by us under the agreement and our belief that Nycomed will diligently commercialize POSIDUR in the additional countries where rights are granted to them, 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 and Nycomed's ability to enroll patients in clinical trials including the BESST trial in a timely manner, DURECT and Nycomed's reliance on third-party contract research organizations for the conduct of clinical trials including 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, 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