DURECT Corporation Announces Completion of Dosing in Cohort 3 of its Phase II Study for its Post-Operative Pain Relief Depot

CUPERTINO, Calif., Sept. 19 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX – News), an emerging specialty pharmaceutical company, announced today the completion of dosing in the third and final cohort of the Phase II dose escalation study in hernia patients in Australia for DURECT's post-operative pain relief depot, SABER(TM)-Bupivacaine. The Company completed enrollment of approximately 60 patients in cohort 3. SABER-Bupivacaine is based on DURECT's patented SABER delivery technology and is intended to be administered around the surgical site after surgery to provide 3 days or more of regional pain relief. The results of cohort 3 are currently being analyzed.

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

"The completion of dosing of the third and final cohort for this Phase II trial for our SABER-Bupivacaine product candidate is an important milestone and advances this product to the next step in the clinical program," stated James E. Brown, DVM, President and CEO of DURECT. "The clinical performance of this product from the second cohort has confirmed our expectation that this product has the potential to be a very significant improvement over the current modalities of post-operative pain therapies on the market. We look forward to announcing the data from this third cohort later this year."

Phase II Study

The Phase II study is a dose escalation trial designed for dose optimization of the product candidate. It includes three cohorts for the treatment of pain in patients following repair of inguinal hernia. Six patients were enrolled in cohort 1, and fifteen patients were enrolled in cohort 2. The following attributes are being evaluated in the study: safety, pharmacokinetics, time to first supplemental analgesic, total supplemental analgesic usage, pain intensity and pain relief.

About DURECT Corporation

DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies that treat chronic debilitating diseases and enable biotechnology products. These platform technologies include the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein and small molecule delivery), the ORADUR(TM) sustained release oral gel-cap technology (an oral sustained release technology with several potential abuse deterrent properties), the DURIN(TM) Biodegradable Implant (drug-loaded implant system), the TRANSDUR(TM) transdermal technology and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also collaborates with pharmaceutical companies to develop and commercialize proprietary and enhanced pharmaceutical products based on its technologies. DURECT has five disclosed on-going development programs of which four are in collaboration with pharmaceutical partners. Additional information

about DURECT is available at www.www.durect.com.

NOTE: SABER(TM), ORADUR(TM), DURIN(TM), TRANSDUR(TM) and MICRODUR(TM) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners.

DURECT Forward-Looking Statement

The statements in this press release regarding DURECT's products in development, anticipated product benefits and product development and clinical trial plans 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 successfully complete clinical trials, complete the design, development, and manufacturing process development of the product candidate, obtain product and manufacturing approvals from regulatory agencies and manufacture and commercialize the product candidate, as well as marketplace acceptance of the product candidate. Further information regarding these and other risks is included in DURECT's Quarterly Report on Form 10-Q for the quarter ended June 30, 2005 filed with the SEC on August 4, 2005 under the heading "Factors that may affect future results."

SOURCE DURECT Corporation

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