



DURECT Announces Start of Dosing in Cohort 3 of Its Phase II Study for Its Post-Operative Pain Relief Depot

CUPERTINO, Calif., July 11, 2005 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) announced today the start 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 anticipates that approximately 60 patients will be enrolled 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 findings of the second cohort indicate the potential for a fundamental breakthrough in post-surgical pain control. In cohort 2, five of the ten patients receiving SABER-Bupivacaine did not take any additional pain medicine in the four days following open hernia surgery," stated James E. Brown, DVM, President and CEO of DURECT.

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 will be evaluated in the study: safety, pharmacokinetics, time to first supplemental analgesic, total supplemental analgesic usage, pain intensity and pain relief.

Cohort 2 Preliminary Results

In June 2005, DURECT announced positive preliminary results from cohort 2 of the on-going Phase II study, reporting that patients who received SABER-Bupivacaine did not use supplementary pain medication until an average of approximately 45 to 60 hours following surgery compared to an average of approximately 2 to 3 hours for the patients in the control group receiving commercial bupivacaine (the current standard of care). These control patients also took on average 4 times more doses of supplementary pain medication as patients who received SABER-Bupivacaine. Five of the ten patients receiving SABER(TM)-Bupivacaine took no supplemental analgesics over the four-day period following treatment. Patients treated with SABER-Bupivacaine also reported better overall mean pain relief and lower pain intensity scores over the four days following treatment compared with patients treated with commercial bupivacaine.

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.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 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 March 31, 2005 filed with the SEC on May 6, 2005 under the heading "Factors that may affect future results."

SOURCE DURECT Corporation

Schond L. Greenway, Executive Director, Investor Relations and Strategic Planning of DURECT Corporation, 408-777-1417

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