DURECT Announces Preliminary Results from Cohort 2 of Its On-Going Phase II Study for Its Post-Operative Pain Relief Depot

CUPERTINO, Calif., June 20 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today positive preliminary results from the second cohort of an on-going Phase II clinical study in hernia patients for DURECT's post-operative pain relief depot product candidate, SABER(TM)-Bupivacaine. 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. These results were presented on June 18th at the International College of Surgeons (ICS) 39th North American Federation Congress in Acapulco, Mexico.

"The preliminary findings from our Phase II study are very significant for the SABER-Bupivacaine development program and DURECT in that they are supportive thus far of all our established clinical objectives for this product candidate of safety, a drug delivery duration of 3 days or more, and in comparison to the current standard of care, improved pain relief and reduction in the use of supplemental analgesic medication. Of note, five of the ten patients receiving SABER-Bupivacaine in cohort 2 of our Phase II study took no supplemental analgesics over the four-day period following treatment," stated James E. Brown, DVM, President and CEO of DURECT.

Phase II Study

This Phase II trial is a dose escalation study underway in Australia. The trial is designed to include 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. Patients in cohort 2 received injections of either SABER-Bupivacaine or commercial bupivacaine (the current standard of care) at the completion of surgery. Patients were allowed to take supplemental analgesic medication to address their breakthrough pain. The following were evaluated in the study: safety, pharmacokinetics, time to first supplemental analgesic, total supplemental analgesic usage, pain intensity and pain relief. The Company anticipates that approximately 60 patients will be enrolled in cohort 3 of the Phase II study.

Cohort 2 Preliminary Results

Safety and Pharmacokinetic Evaluation

No significant clinical adverse events or local or systemic toxicity were observed, and the injections were well tolerated. Pharmacokinetic evaluation of plasma bupivacaine concentrations showed that SABER-Bupivacaine achieved its target delivery profile of providing a delivery duration of over 72 hours with no burst upon injection.

Pain Management Assessment

Using standardized pain evaluation methodology that has been recognized by

regulatory authorities to measure pain relief, patients treated with SABER-Bupivacaine reported better overall mean pain relief over the four days following treatment compared with patients treated with commercial bupivacaine (Control). Patients treated with SABER-Bupivacaine also reported lower pain intensity scores than the Control group using a visual analog scale (VAS) over the four days following treatment.

Use of Supplemental Analgesics

Patients treated with SABER-Bupivacaine took fewer doses of supplemental analgesics during the four days following treatment compared with patients in the Control group. In addition, the length of time prior to the first dose of supplemental analgesics was greater for patients treated with SABER-Bupivacaine than for patients in the Control Group.

The following tables below provide a summary of the preliminary results from cohort 2:

Table 1 - Pain Management Assessment over 4 Days

	Study Product (Bupivacaine injection dose in mg.)	Mean Overall Pain Relief over 4 Days	Mean VAS Summed Pain Intensity Score (+/-SD) At Rest	Coughing
Group 1	SABER-Bupivacaine + Saline (638mg) - (n=5)	A Lot	313+/-423	781+/-521
Group 2	SABER-Bupivacaine + Commercial Bupivacaine (688mg) - (n=5)	A Lot	636+/-514	1,585+/-1,240
Control	Commercial Bupivacaine (75mg) - (n=5)	Some	2,770+/-1,644	4,387+/-1,033

Table 2 - Mean Time to Supplemental Analgesic (Hrs.) and Mean Supplemental Analgesic Dosage taken over 4 Days (No. of Doses)

	Study Product (Bupivacaine Injection Dose in mg.)	Mean Time to Supplemental Analgesic (Hrs.)	Mean Supplemental Analgesic Doses over 4 Days (No.)
Group 1	SABER-Bupivacaine + Saline (638mg) - (n=5)	60.4	2.6
Group 2	SABER-Bupivacaine + Commercial Bupivacaine (688mg) - (n=5)	44.9	2.4
Control	Commercial Bupivacaine (75mg) - (n=5)	2.3	11.0

NOTE:

1) Five of the ten patients receiving SABER(TM)-Bupivacaine (> or = 638 mg) took no supplemental analgesics over the four-day period following treatment.

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.

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

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