DURECT Announces Positive Preliminary Results From Its Phase II Study for Its Post-Operative Pain Relief Depot

CUPERTINO, Calif., Oct 18, 2005 /PRNewswire-FirstCall via COMTEX News Network/ — DURECT Corporation (Nasdaq: DRRX) announced today positive preliminary results from the Phase II dose escalation study (Cohorts 1-3) in hernia patients in Australia for DURECT's post-operative pain relief depot, 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 to a group of surgeons attending the American College of Surgeons conference in San Francisco, CA.

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

"We observed clear dose proportional pharmacokinetics in this study whilst giving a continuous and stable delivery of bupivacaine over a period of four days, with safety was demonstrated across all observed doses. Additionally, this study provides promising preliminary data for SABER-Bupivacaine in those areas considered clinically significant for post-surgical pain management, namely reduced pain intensity, improved pain relief and a reduction in use of supplemental opioid medication, providing encouraging results for the possibility to reduce opioid-related side effects for post-surgical patients," stated Guy Patrick, MD, PhD, Premier Research Group plc., the physician who oversaw the conduct of the Phase II study for DURECT.

"The preliminary findings from our Phase II study are very significant for the SABER-Bupivacaine development program and DURECT in that they are supportive of our established clinical objectives for this product candidate," stated James E. Brown, DVM, President and CEO of DURECT. "The data we have seen to date support our continued efforts to move this program into late-stage clinical development and indicate that SABER-Bupivacaine, if approved, has the potential to be a significant improvement over the current post-operative pain therapies on the market."

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 and sixty patients in cohort 3.

Preliminary data indicate that all primary endpoints for the study were achieved, which include:

— 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.
— Safety — No significant clinical adverse events or local or systemic toxicity were observed, and the injections were well tolerated by the patients.
— Established dose range for the product.

Other Preliminary Observations (Cohort 2 and Cohort 3, N=75)
— Using standardized pain evaluation methodology that has been recognized by regulatory authorities to measure pain relief, patients treated with SABER-Bupivacaine reported a trend for better overall mean pain relief over the four days following treatment compared with patients treated with commercial bupivacaine (Control).
— The SABER-Bupivacaine group had less pain intensity and required less supplemental opioid analgesics over the four days following treatment as compared to the Control group.
— The total numbers of doses of supplemental medication (opiate and non-opiate) were the same in both treatment groups; however, the SABER-Bupivacaine group utilized fifty percent (50%) less supplemental opioid medication for post-operative pain over the four days following treatment compared with the Control group.

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, product development 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 September 30, 2005 filed with the SEC on October 13, 2005 under the heading “Factors that may affect future results.”

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