DURECT Initiates Phase II Clinical Program for Post-Operative Pain Relief Depot

CUPERTINO, Calif., Oct. 25 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today the initiation of a Phase II clinical study for its post-operative pain relief depot (SABER-bupivacaine), a sustained-release formulation of a local anesthetic using the Company's SABER(TM) drug delivery system. SABER-bupivacaine is designed to be administered, via injection, around an incision site following surgery for post-operative pain relief. One dose of SABER-bupivacaine is intended to provide up to 72 hours of regional pain relief.

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

"On the strength of the results of our Phase I data that showed good safety and tolerability as well as up to 3 days of drug release, we are very excited to advance this program into Phase II development. We believe that our post-operative pain relief depot, once approved, will reduce opioid consumption and their associated side effects and hospital stays for numerous patients that undergo surgery each day," said James E. Brown, President and CEO of DURECT.

DURECT worked with an advisory panel of leading clinical physicians and experts in the field of post-surgical pain management to develop the protocol for the Phase II trial. The Company anticipates that the trial will enroll approximately 65 patients, with an option to enroll an additional 30 patients, for a possible total enrollment of 95 patients in the trial. The Phase II trial will be a dose escalation study, conducted in three parts. All parts of the trial will be conducted in Australia as an open label study for the treatment of pain in patients following repair of inguinal hernia. Patients will be administered with SABER-bupivacaine at the completion of surgery, and the trial will evaluate the safety and efficacy of the injection. The primary end points for the trial will include a pharmacokinetic evaluation of plasma bupivacaine levels, time to first supplemental analgesic, analysis of the sum of pain intensity and analysis of total pain relief. The information on dose response collected in this study will be used in future Phase III trials to demonstrate the safety and efficacy of the SABER-bupivacaine product.

Physician-based market research conducted by the Company indicated that this product may represent an innovation over currently available post-operative pain relief therapies. The Company believes this product could potentially reduce hospital stays and the amount of traditional post-surgical pain medications needed by patients, as well as the side effects that result from the use of concomitant opioid medications. The Company believes that there are currently more than 25 million surgical procedures performed annually in the US for which this product could be potentially used.

About DURECT Corporation

DURECT Corporation is a 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) and the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system). DURECT also partners 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 three are in collaboration with pharmaceutical partners. Additional information about DURECT is available at www.www.durect.com.

NOTE:

SABER(TM), ORADUR(TM), DURIN(TM) and MICRODUR(TM) are trademarks of DURECT Corporation.

The statements in this press release regarding DURECT's products in development, product development plans, clinical trials and potential product benefits and markets 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 its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies as well as marketplace acceptance of its products. Further information regarding these and other risks is included in DURECT's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 filed with the SEC on March 11, 2004, DURECT's Quarterly Report on Form 10-Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

The SABER-bupivacaine product referred to in this press release is under development and has not been submitted or approved for commercialization by the US Food and Drug Administration or other health authorities.

SOURCE DURECT Corporation

/CONTACT: Schond L. Greenway, Mxecutive Director, Investor Relations and Strategic Planning of DURECT Corporation, +1-408-777-1417/
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