



DURECT Initiates Human Clinical Testing for Its Post-operative Pain Relief Depot Using the SABER(TM) Delivery System

CUPERTINO, Calif., June 10 /PRNewswire-FirstCall/ —

DURECT Corporation (Nasdaq: DRRX) announced today that the Company has commenced clinical testing of its post-operative pain relief depot product.

DURECT's post-operative pain relief depot product, a sustained release injectible using the SABER(TM) delivery system and a local anesthetic, is designed to be administered locally around a surgical site after surgery for post-operative pain relief. This pain relief product is intended to provide local analgesia for up to three days, which coincides with the greatest need for post surgical pain control in most patients. Bupivacaine, the active agent for the product, is currently FDA-approved for use in hospitals as a local anesthetic typically administered to patients in the post-surgical setting.

One dose of DURECT's post-operative pain relief product is intended to provide up to 72 hours of regional pain relief, compared to conventional practices, which include both opioid and non-opioid medications. Currently, there are more than 20 million surgical procedures performed annually in the US for which this product could be potentially utilized.

"Our goal is to deliver an appropriate local anesthetic to the surgical wound area, where adequate pain control can be achieved with minimal exposure to the remainder of the body. In our market research, physicians indicated that this product concept would represent an innovation over currently available post-operative pain relief therapies," stated James E. Brown, President and Chief Executive Officer of DURECT. "This product could potentially reduce hospital stays, the amount of traditional post-surgical pain medications needed by patients, as well as with their associated side effects resulting from the use of concomitant opioid medications. The start of human clinical trials for this product is an important milestone for DURECT and our SABER development programs."

Post-operative Pain Study

The initial human clinical tests have been initiated in normal, healthy volunteers in Europe. The objectives of the clinical study are to determine the safety and tolerability of SABER and SABER-bupivacaine and to determine the sensory effects of SABER-bupivacaine administered subcutaneously. The product will be developed using DURECT's patented SABER drug delivery system. The SABER delivery system is a patented, biodegradable controlled-release technology that can be formulated for parenteral, oral, dermal or other route of administration of active agents for human pharmaceutical and veterinary applications.

Special Note About Forward-Looking Statements

The statements in this press release regarding DURECT's products in development, clinical trials and 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 of its products, successfully complete clinical trials, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage relationships with third parties, finance its activities and operations, as well as marketplace acceptance of DURECT's 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, 2002 filed with the SEC on March 14, 2003, DURECT's Quarterly Report on Form 10Q and other periodic reports filed with the SEC under the heading "Factors that may affect future results."

NOTE: SABER(TM) is a trademark of DURECT Corporation. DURECT's post-operative pain product 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

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