



# DURECT Announces Positive Clinical Results for its Post-operative Pain Relief Depot using the SABER(TM) Delivery System

CUPERTINO, Calif., Nov. 6 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) announced today that the Company has completed its first study in humans with its post-operative pain relief depot product. DURECT's post-operative pain relief depot product, a sustained release injectable using the SABER delivery system and a local anesthetic, is designed to be administered locally around a surgical site after surgery for post-operative pain relief. One dose of DURECT's post-operative pain relief product is aimed at providing up to 72 hours of regional pain relief, to reduce hospital stays and opioid consumption.

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

“We are very pleased with the good biocompatibility we have seen with the SABER depot in these subjects,” stated Dr. James E. Brown, President and CEO of DURECT. “The plasma concentration of drug measured in these subjects allowed us to estimate the extent and rate of absorption in these subjects. This study increased our confidence in the capabilities of the SABER depot technology, and is very positive for further development of a SABER bupivacaine product.”

## Post-operative Pain Depot Study

The initial human clinical tests were completed in 12 normal, healthy volunteers in Europe. The objectives of the clinical study were to determine the safety and tolerability of SABER and SABER-bupivacaine, as well as evaluate the pharmacokinetics of our SABER product versus current treatment methods, which included bupivacaine and ropivacaine. The subjects in this study were injected with a SABER placebo compared with a SABER depot containing a low dose of bupivacaine. The extent of absorption of the drug was 100% and the rate of absorption of drug from the depot was found to be continuous for three days as designed. The release of our drug product over 3 days is a significant improvement over the current treatment methods, which typically lasts for 4 to 6 hours.

Physicians that participated in the market research surveys for this product indicated that this product concept would represent an innovation over currently available post-operative pain relief therapies. 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. Currently, there are more than 20 million surgical procedures performed annually in the US for which this product could be potentially utilized.

DURECT Corporation ([www.durect.com](http://www.durect.com)) is pioneering the development and commercialization of pharmaceutical systems for the treatment of chronic debilitating diseases and enabling biotechnology-based pharmaceutical products. DURECT's goal is to deliver the right drug to the right site in the



right amount at the right time. In addition to its rights to the CHRONOGESIC(R) product, DURECT owns three proprietary drug delivery platform technologies, including the SABER(TM) Delivery System (a patented and versatile depot injectable useful for protein delivery), the MICRODUR(TM) Biodegradable Microparticulates (microspheres injectable system) and the DURIN(TM) Biodegradable Implant (drug-loaded implant system).

NOTE: CHRONOGESIC(R), SABER(TM), MICRODUR(TM) and DURIN(TM) are trademarks of DURECT Corporation.

The statements in this press release regarding DURECT's products in development 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 development of its products, manufacture and commercialize its products, obtain product and manufacturing approvals from regulatory agencies, manage its growth and expenses, 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."

CHRONOGESIC is under development by DURECT 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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