



# DURECT Initiates Manufacture of Clinical Product for its CHRONOGESIC(R) (Sufentanil) Pain Therapy Product

CUPERTINO, Calif., Oct 9, 2003 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has initiated manufacture of clinical product for its anticipated pharmacokinetic study and other initial clinical studies in the Phase III program for its CHRONOGESIC(R) (sufentanil) Pain Therapy product using the Company's new terminal sterilization manufacturing process.

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

"Today, we are pleased to report that we have started the manufacture of product to supply the initial clinical trials for our CHRONOGESIC product. This is an important milestone for our CHRONOGESIC program," stated James E. Brown, DVM, President and CEO of DURECT. "The credit for this accomplishment is due to the experience, ingenuity and hard work of our employees who are committed to the development of a much needed product to treat patients suffering from chronic pain. Going forward, we intend to continue executing on our plans to complete the tasks necessary to move our CHRONOGESIC product back into the clinic."

The CHRONOGESIC product is intended to target patients with opioid responsive chronic pain that results from a variety of causes. The CHRONOGESIC product is designed to deliver sufentanil continuously for three months of pain therapy. Sufentanil is an opioid that is currently used in hospitals as an analgesic agent. Chronic pain is a significant problem associated with chronic diseases, including cancer and various neurological and skeletal disorders. Chronic nonmalignant pain affects as many as 34 million Americans annually. In addition, the National Cancer Institute estimates that 8.4 million Americans alive today have a history of cancer. Sales of opioids for the treatment of malignant and nonmalignant pain currently exceed \$3 billion.

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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