DURECT Corporation Completes Validation of Terminal Sterilization Manufacturing Process for its CHRONOGESIC (sufentanil) Pain Therapy Product

CUPERTINO, Calif., Sep 2, 2003 /PRNewswire-FirstCall via COMTEX/ — DURECT Corporation (Nasdaq: DRRX) today announced that it has completed validation of the terminal sterilization manufacturing process for its CHRONOGESIC (sufentanil) Pain Therapy product.

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

“Our stated objectives this year were to implement some necessary design and manufacturing enhancements to our CHRONOGESIC product and subsequently restart our clinical program in the second half of 2003. In July, we announced that we have completed the system optimization of our CHRONOGESIC product and today, we are pleased to report that we have implemented both our design enhancements and new terminal sterilization manufacturing process,” stated James E. Brown, DVM, President and CEO of DURECT. “During the remainder of this year, we intend to manufacture product to support clinical trials for our CHRONOGESIC product and move this product back into the clinic.”

Terminal sterilization is the process of sterilizing the final packaged product. In contrast, an aseptic packaging process requires individual product components to be sterilized separately and the final package assembled in a sterile environment. Terminal sterilization of a product provides greater assurance of sterility than an aseptic process. In general, the ability to use a terminal sterilization method can reduce various manufacturing costs for our CHRONOGESIC product when compared to an aseptic manufacturing process.

DURECT Corporation (www.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

Schond L. Greenway
Senior Director
Investor Relations and
Strategic Planning of DURECT Corporation
408-777-1417
/Photo: NewsCom: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO
AP Archive: http://photoarchive.ap.org
PRN Photo Desk, +1-888-776-6555 or +1-212-782-2840

http://www.www.durect.com